MIGRATION

Frequently Asked Questions

SunChemical®
a member of the DIC group
DIC Color & Comfort

Migration - Frequently Asked Questions

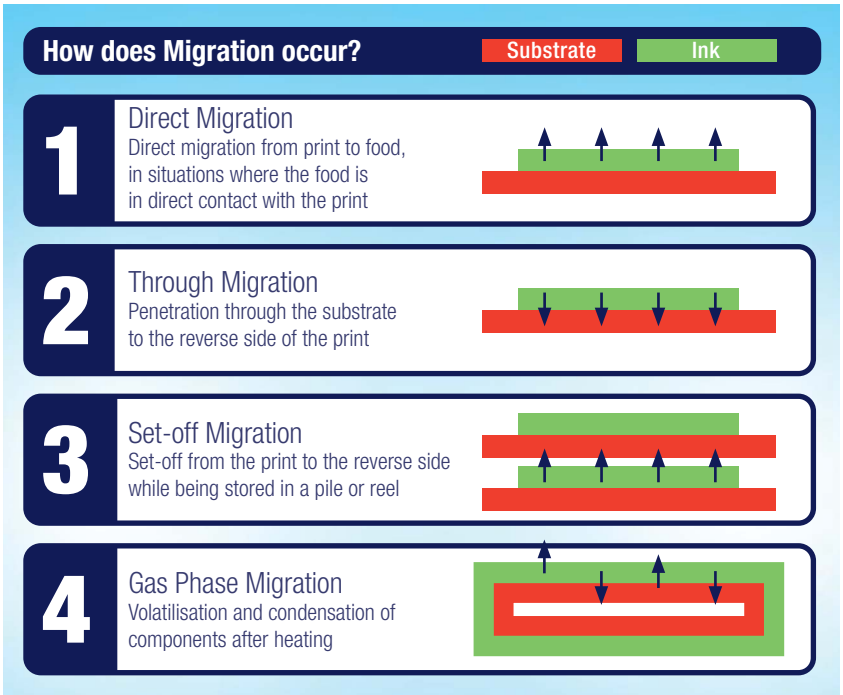
Contents

What is migration?

Migration is the transfer of substances from the packaging to the packaged goods. These substances may not always be detected in organoleptic testing (odour and taste tests) or when consumed, but may be found by sensitive chemical analysis.

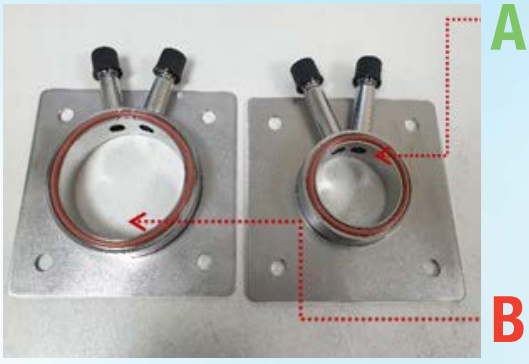
Why do I need to consider migration of ink and coating components in packaging printing?

A migration risk may exist when printed inks, coatings or adhesives are in close proximity to a packaged food and where there is no functional barrier between the packaging and contents.



Where the design, production, storage or use of a package includes a significant risk of transfer of unwanted chemicals to the packaged product, there is a need to minimise that risk by the use of best practices.

Migration Test Cell



- **A:** Total print coverage 50 cm^2 --> 25 cm^2 on either side of the ring
- **B:** Total print coverage 100 cm^2 --> 50 cm^2 on either side of the ring

How do you measure migration and in what units?

Migration testing is best undertaken by an expert accredited laboratory. Fully commercial and representative production packaging is usually required. Such laboratories use sophisticated migration cells and highly sensitive chromatography and mass spectroscopy equipment. Measuring migration from printed packaging is a much more complex task than assessing the impact of odour or taint. Migration is measured by determining the identity, and amount of materials that transfer from the packaging sample, ideally into a control sample of the actual food. In practice, analysis of food samples is difficult and so food simulants are used to mimic the nature of the food itself.

Results are usually quoted in milligrams (mg) per kg of food (parts per million; ppm), or micrograms (µg) per kg of food (parts per billion; ppb).

What are food simulants and how are they used?

Food simulants are typically simple solvents used to mimic the behaviour of foodstuffs, and facilitate the analysis of components which transfer from packaging into the packaged food. Accelerated testing is also used to obtain migration results within a reasonable time period, rather than waiting until the end of the shelf storage life of the packaged products. Analytical methods to separate, detect and identify migrants include, in particular, gas and liquid chromatography, with a variety of detectors, including UV and mass spectroscopy.

Migration testing can take some weeks to complete due to sample preparation times before and after the period in the migration cell. Different packaging scenarios are possible (area of print, weight of food simulant, contact time and temperature), and care should be taken to select the appropriate scenario which represents the actual conditions during use.

Intentionally using more extreme food simulants or temperature – time conditions may cut down on the number of migration tests that are needed. Since the testing with simulant is intended as a worst case screening test for migration, results obtained in the packaged foodstuff itself will always take precedence.

In the European Union, food simulants and their use are prescribed in the Plastics Regulation (EU) No 10/2011. Simulants A, B, C, D1 & D2 and E are designated as suitable for testing of food contact materials, depending on the nature of the foodstuff that is to be packaged. The following are commonly used:

- Water
- 3% Aqueous acetic acid, for acidic foods
- Aqueous ethanol at varying concentrations, e.g. 20% to simulate clear drinks, 50% for dairy products and 95% for fatty foods
- Isooctane and olive oil may also be used, with the latter chosen to represent all vegetable oil products
- Poly(2,6-diphenylphenylene oxide) known as Tenax® is a highly porous polymer resin that is used as a simulant for dry food as it is a very effective absorbent for volatile or semi-volatile materials

The time and temperature combinations to be used to represent the conditions experienced by the packaged food during migration testing are described in the EU Plastics Regulation; however, it should be highlighted that both the simulants and accelerated testing conditions have been designed for evaluating plastic food contact materials and there may be some issues when applied to non-plastic materials, such as paper and board, and to inks and coatings. Results are usually calculated using the EU standard model, whereby the average citizen is assumed to consume 1kg of food daily, which is wrapped within 600 cm^2 or 6 dm^2 of printed packaging.

For the United States, the FDA describes, in 21 CFR 175.300, extraction with combinations of three solvents at various temperatures and times to simulate the different food types and conditions of use:

- Water
- Heptane
- 8% Alcohol

The Chinese rules for migration testing, described in National Standard GB 31604. 1-2015, are generally similar to those in the European Plastics Regulation; however, there are some differences, for example testing contact times are often longer, and 4 % aqueous acetic acid is prescribed as the acidic food simulant.

What level of migration is acceptable?

The determination of an 'acceptable' maximum level of migration is based on the toxicological profile of the migrant material and the availability and expert assessment of the toxicological data. In all cases of migration the migrants must be identified in order to carry out a risk assessment. It is common practice to use Specific Migration Limits (SMLs) that have been established by competent authorities, even though they may have been set for different food contact materials or uses.

Within the European Union, Switzerland and United Kingdom, the generic migration limits indicated in the table are normally used:

Measured level	Description	Note
< 10 ppb	Detection limit	1
10 – 50 ppb	Not genotoxic	2
> 50 ppb	Evaluation needed	3

- **Note 1:** Even if the level of migration is less than 10ppb (the detection limit) there must be no material detectable with potential genotoxic or carcinogenic activity.
- **Note 2:** Absence of genotoxicity as determined by mutagenicity testing in accordance with EFSA guidance.
- **Note 3:** The toxicological profile must be evaluated by a competent expert and approved at this level of migration. For example, one of the migrants may be listed with a specific migration limit.

The FDA's Toxicity Guidelines have similar requirements, depending upon the level of exposure in the diet:

Dietary exposure	Data
≤ 0.5 ppb	No data required (Threshold of Concern)
> 0.5 – 50 ppb	Not genotoxic (note 1)
> 50 ppb – 1 ppm	Additional data (note 2)

Note 1: As determined in two in vitro mutagenicity tests.
Note 2: Additional in vivo genotoxicity and sub-chronic toxicity testing.

What are 'low migration' products?

The term "low migration" was introduced to denote products specifically designed and formulated to achieve very low levels of migrating components during the use of printed packaging. It was originally applied to UV curing and sheetfed offset inks and coatings, since these products often consisted of components that had not been previously evaluated for use as food contact materials, and for which a 10 ppb or 50 ppb migration limit typically applied. A number of consumable products (founts and wash-ups) were also developed to minimise migration in use. This low migration terminology never really caught on for flexible packaging products, since the majority of the components used had already been assessed as (plastic) food contact materials and assigned relatively large SMLs.

Unfortunately, a number of opportunistic suppliers began to use the low migration description for products which did not have low levels of migrating components, and in extreme cases, regarded compliance with the Overall Migration Limit (< 60 ppm) as being low migration. This approach has so devalued the use of the term "low migration" that EuPIA now recommends using "migration compliant" instead.

How does "low migration" relate to low taint and odour?

Early generation products designed specifically to limit migration potential were usually by their nature also designed for low taint and odour. The expression "low migration" when applied to ink products is not defined in regulation and can be interpreted in different ways by different members of the supply chain. Neither does it give an assurance that a product has specific organoleptic properties. We therefore recommend to always specify low taint and odour in addition to migration performance.

The availability of migration compliant materials does not mean that routine testing for odour and taint properties should be abandoned. Testing for freedom from organoleptic impact should still be an important part of product quality assessment programmes. Note also, that a material described as "low taint" and "low odour" doesn't necessarily have low migration properties and may not be capable of producing compliant packaging.

How do I judge odour and taint?

"Low Odour" and "Low Taint" are expressions that have been used in the packaging industry for many years. There are methods and procedures for testing both printed packaging and the various components used in their production, with respect to this issue, to ensure that under normal or foreseeable conditions of use, the organoleptic characteristics of the packaging are unaffected. Packaging suppliers can meet the demands of the packaging buyer, or end user in this respect, by using a suitable method and frequency of test.

European Standards EN 1230-1:2009 (Paper and board intended to come into contact with foodstuffs. Sensory analysis. Odour.) & EN 1230-2:2009 (Paper and board intended to come into contact with foodstuffs. Sensory analysis. Off-flavour (taint).) specify the test methods for assessment of the odour released by a paper or board sample and whether a sample contains substances which may be transmitted through the air space to a test substance and affect its taste. They are applicable to all kinds of paper and board, including coated and/or printed material, intended to come into direct or indirect contact with foodstuffs.

International Standard ISO 13302:2003 (Sensory analysis - Methods for assessing modifications to the flavour of foodstuffs due to packaging) describes two complementary tests for the assessment of the inherent odour of the packaging material under test (odour test) and the change of flavour of a foodstuff after direct or indirect contact with the packaging material under test in actual conditions or in simulated conditions (contact test).

Rather than sending samples to external testing laboratories, a common approach is to establish trained sensory panels at packaging production sites. A minimum of 6 members is recommended, with statistical validation, and the median score is typically used.

These methods enable a numerical value to be assigned to allow comparative assessment of the taint and odour of the packaging. The legislative requirement not to cause a deterioration in the organoleptic characteristics of the food is judged on this basis. A five-point scale is commonly used for sensory scoring, with a pass mark typically between 2.0 and 2.5 depending on customer specification.

Score	Description
0	No perceptible off-odour / no perceptible off-taste
1	Off-odour just perceptible / off-taste just perceptible
2	Weak off-odour / weak off-taste
3	Clear off-odour / clear off-taste
4	Strong off-odour / strong off-taste

Why measure migration?

Migration should be measured to confirm that packaging complies with the relevant regulations and ensure the safety of the consumer, in line with risk assessment and Good Manufacturing Practice. Since migration testing is complex, costly and time consuming, it is possible to use calculations or modelling as an alternative to demonstrating compliance, so long as the results are at least as severe as the migration testing. There is a growing use of diffusion modelling software, which utilises diffusion and partition coefficients to calculate the maximum migration for a particular substance incorporated in a food contact material.

However, it is advisable from time to time to compare the results from modelling with actual results obtained from analytical testing to verify the use of modelling as a compliance tool, particularly since some models may not adequately address set-off migration.

Is migration time dependent?

Yes, migration is a time dependent phenomenon. However, there are many 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 migrates?

The following is a non-exhaustive list of typical potential migrants:

- Solvents, washes and cleaning chemicals
- Oils and greases
- Plasticisers from plastics or inks
- Residual monomers from plastics, inks, coatings or adhesives
- Breakdown products from inks and/or coatings following curing or drying
- Hydrocarbon distillates from conventional inks
- Non reacted materials in the case of insufficient UV or EB curing
- UV photoinitiator
- Any other unwanted low molecular weight or mobile molecules

How do I ensure prevention of health hazards that may result from migration?

Ensuring full and continuous compliance of the packaging materials with all relevant food contact legislation should prevent health hazards due to migration. Alternatively, where the 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, where legislation covering composite materials is lacking or where an efficient functional barrier cannot be applied.

Producing compliant packaging is not simply achieved by moving to migration compliant inks and coatings. Migration from many sources can affect the packaged goods and the whole process from concept to distribution needs to be considered including particularly post print processes such as lamination, heat-sealing etc.

An unprinted inner packaging layer with an absolute or functional barrier may allow the use of standard inks and coatings, but even then, the risk that migration can occur by a different mechanism should be assessed. Examples of absolute barriers include glass bottles, metal cans and pouches or cartons that contain a continuous layer of aluminium. Some films, e.g. PET and to a lesser extent OPP, may have barrier properties, depending on thickness. In general polyolefin films such as PE or HDPE, unless specially treated, have poor barrier properties to many chemical migrants, even though they function well as moisture barriers. Testing the packaging (including the barrier) in simulated or actual conditions of use may be needed to determine the effectiveness of the barrier and confirm compliance.

What are my responsibilities as a packaging designer or manufacturer?

In general terms, legislation on food packaging covers the guiding principle that food packaging should not transfer materials to the packaged food in quantities that could bring about a change in the nature, substance or quality of the food and must not be injurious to health. This principle is to be obeyed even if no specific guidelines exist.

The objective of achieving compliant and safe packaging requires all stakeholders in the packaging design and production chain to work together according to Good Manufacturing Practice (GMP). It is expected that specifications are provided upwards in the supply chain (so from the food manufacturer to the raw material suppliers) and relevant technical information is shared downwards. GMP provides a framework of rules for all stakeholders involved in the development of packaging and requires appropriate selection and use of materials and articles intended to come into contact with food. Working specifications, quality assurance, control mechanisms and traceability should be established and maintained as best practice.

Where the design, production, storage or use of packaging includes a significant risk of transfer of unwanted chemicals to the packaging product, there is a need to minimise that risk by the use of best practices. A risk may exist when inks, coatings or adhesives are in close proximity to the packaged foodstuff and where there is no functional barrier between the packaging and the contents. Careful risk analysis can provide a measurement of the level of these risks. A number of issues that may need to be addressed are covered elsewhere in this guide.

Where there is a risk of "set-off" on the reverse side of the print, a functional barrier should be included in the package design. Use of a coating or over-print varnish will not normally prevent migration. Set-off can be controlled to some extent by adopting simple procedures, and by ink and coating selection. When conventional oil-based inks are used spray powder and/or water-based coating can help reduce the risk. With UV curable inks and coating, the best possible cure should be achieved.

The converter must ensure that the applicable restrictions, migration limits and other limitations are fully respected. This can be achieved by:

- Appropriate pack 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 (working hygiene)

How does Sun Chemical help to ensure compliance?
Sun Chemical's food packaging inks are manufactured in accordance with the requirements of EuPIA Good Manufacturing Practice (www.eupia.org). Raw materials are carefully selected and our packaging inks are formulated so that the levels of heavy metals and environmentally hazardous substances in the print are minimized to allow the printed packaging to meet the requirements of the Packaging and Packaging Waste Directive (94/62/EC) and the Regulations of the Coalition of North Eastern Governors (CONEG).
Odorous raw materials are avoided and relevant legislation is followed.

Sun Chemical takes its product stewardship responsibility very seriously and works hard to keep abreast of all current and future legislative changes and support customers in managing their compliance on a continuous basis.

Printing inks, coatings and adhesives, unless specifically designed for the purpose, should not under normal circumstances come into direct contact with packaged foodstuffs. Therefore, printed food packaging should be printed in such a manner that set-off during and after the printing process is avoided as far as is practically possible in order to ensure that the surface of the packaging in contact with the packaged product is free of printing inks and coating.

However, every package is different, so the outcomes may differ according to the perceived risk of transfer of material from the packaging to the food and the barrier properties of the packaging materials used. End use properties may also influence the choice, for example if the food is to be hot filled or heated in the packaging, which might increase migration. While inks and coatings for compliant food and sensitive packaging are specially made for this purpose they may not achieve compliance in extreme cases and package and print area design will need to be carefully considered.

Are there special requirements for direct food contact inks and coatings?

In some instances the print on the packaging is intended to be in very close or direct contact with the packaged goods. This is referred to as Direct Food Contact (DFC). In these circumstances it is necessary to make a rigorous risk assessment due to the very close proximity of the ink to the packaged food and greater risk of ink component migration. Due to the wide range of scenarios such as the specific nature of the packaged goods and contact time, which may be from a few minutes to many months, the feasibility and selection of suitable ink products needs to be made on a case-by-case basis.

Inks for direct food contact will almost always require a more rigorous process of selection of raw materials and formulation design, to minimise Non Intentionally Added Substances (NIAS) such as impurities. In addition, a more controlled process for manufacture, including contamination control (from previous batches & from cleaning materials) and hygiene control, needs to be implemented. In specific low risk scenarios the use of standard migration compliant products may be appropriate subject to specific migration testing and risk assessment. In most cases though printing should be conducted using specifically formulated inks and coatings, possibly using approved food additives. In all cases it will be necessary to seek expert advice and recommendations from ink suppliers and conduct a risk assessment as without this there is a high probability that the printed packaging will not comply with the relevant legislation.

What do I need to consider if the packaging is to be used at elevated temperatures (microwave, oven-able, pasteurisation, retort etc.)?

A key packaging design trend emerging in recent years has been the development of convenience packaging: “ready meals” that are microwaved, oven cooked or “boil in the bag“ in their original store packaging, retail and home use of “cook-in-the-tray” bakery items etc. There is also significant growth in extended shelf-life food packaging incorporating retort and pasteurisation processes prior to sale. An increasing proportion of this packaging is now printed in some way and there are growing concerns about the design of such packaging and particularly the risk of potential impact of the packaging on the contained foodstuffs during the cooking process.

It is always a minimum and mandatory requirement to ensure consumer safety when selecting materials for packaging. An additional cooking process being included in a pack design adds to that demand. Foodstuffs packaged in boxes or trays, that are to be cooked by microwaving or in an oven, can be assumed to be subject to a number of conditions, including:

- Close proximity of print to foodstuff
- Long-term storage (extended shelf-life products)
- A wide variety of (sometimes uncontrollable) cooking times and temperatures
- Exposure to high temperatures when cooked in an oven
- Localised heating in a microwave oven, especially if the packaging includes a susceptor*

*Please note that if the packaging construction includes a susceptor, excessive localised heating can lead to breakdown of materials used in the packaging with currently unknown consequences; printing on, or close to, the susceptor should be avoided.

Under these conditions, careful attention must be given to packaging design and selection of materials, since there is increased potential for migration from the packaging due to the high temperatures which can be attained during microwave and oven cooking. Potential migrants include thermal breakdown products from pigments, volatile components from the ink and coating vehicle systems, low molecular weight components of inks, coatings, adhesives and the substrate and by-products from the UV curing process. Minimising the amount of print on the package will also help to limit any risk.

Not all colours are suitable for high temperature applications and only those based on heat stable pigments are recommended. Even then, exposure to temperatures above 180°C should be avoided. Migration compliant coatings should be used with the inks where gloss, controlled slip properties and print protection are required, such as with migration compliant oleoresinous conventional offset inks. The use of water-based coatings should be tested in the specific application due to the risk of melting and break down in elevated temperature conditions. In this case, a cross-linkable water-based coating may be used. In UV printing, only specific products are suitable for microwave applications and specific advice should be sought.

There have been a small number of reported instances of a potential fire hazard when containers printed with a printing ink incorporating carbon black pigment are heated in a microwave oven. Although these incidents appear to be rare, they have not been subjected to definitive technical evaluation. Consequently, Sun Chemical advises that products printed with carbon black containing inks, intended for microwave applications, should be assessed under appropriate conditions of use to ensure they are fit for that specific purpose. If necessary a trichromatic black blend can be used in place of a carbon black based ink.

Knowledge regarding the performance of different types of printed material in elevated temperature applications is far from complete. It is always recommended that packaging produced for elevated temperature applications is tested to ensure that it complies with legal requirements. It is the printer converters' and packaging distributors' responsibility to ensure the packaging has been fully assessed for risk and that the packaging produced meets regulatory requirements for its end use. Therefore, migration testing under appropriate conditions of use is strongly recommended before proceeding with commercial printing of packaging for microwave or ovenable applications.

How can I demonstrate that my packaging is compliant?

Migration testing is a key step in the assessment of the suitability and eventual compliance of the packaging design and in the selection of appropriate materials following the design and risk assessment steps. Ideally, migration testing of the printed package should be conducted using the packaged foodstuff but, as that is often very difficult, prescribed simulants for the particular foodstuff are normally used. This type of testing is usually designed to simulate the "worst case scenario" thus potentially allowing evidence of compliance to be applied across a range of printed products using similar materials or combinations of materials and packaging structures as part of a risk assessment.

Migration cells for Tenax®

Data may be reported as 'global migration' giving a preliminary assessment of potential migration levels and thus compliance. However, only 'specific migration' data reported against the applicable Specific Migration Levels (SML's) for each chemical component can give a comprehensive verification of compliance. Testing is best conducted in an expert third party accredited laboratory that specialises in this type of work.

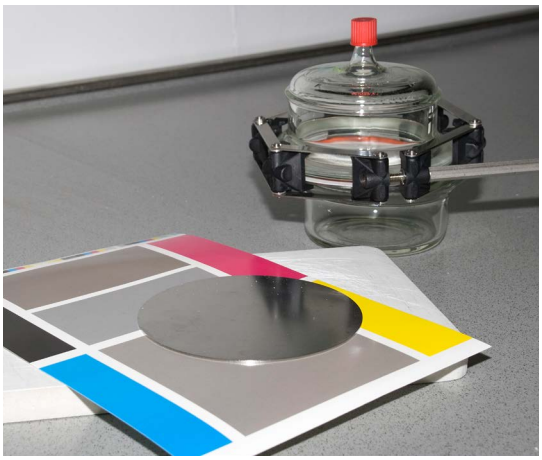
Under normal circumstances Sun Chemical, as the ink and/or coating supplier, will provide compositional information to the test house or analytical laboratory, under non-disclosure agreement, to allow effective testing and reporting of results. Sun Chemical has extensive knowledge in this area, built up over more than 25 years, and can conduct ISO 17025 accredited testing, the highest level of accreditation for analysis in this area. We nevertheless advise that independent verification of compliance of commercial print should be sought.

Sun Chemical has close working relationships with a number of external migration testing laboratories. Please contact Sun Chemical for further information on these services. Note: print samples for migration testing need to be carefully selected, collected and protected to avoid contamination prior to analysis. Please seek advice from the testing laboratory.

What do I need to consider when testing for migration?

Prior to conducting a migration test it is necessary to define exactly what will be tested as this will influence the interpretation of the results. In a multi-component packaging structure, (for example cereal box with inner bag) the outer printed packaging layer itself (printed or non- printed side), could be tested, or the whole packaging as it will be used (that is including the unprinted inner packaging layer). This information is essential, as the results could be misleading, depending on the test used and how the results are calculated. In particular, tests made on the non-printed side of a single layer package may be a good indicator for risk assessment, but the same test run on a printed outer layer in a multilayer structure, whilst giving an indication of the level of material that is available to migrate, may not be representative of the conditions of use as it does not take into account the properties of any inner packaging layers (printed or unprinted).

Additionally, migration results are usually reported according to a standard surface area to food weight model (1 kg of food in 6 dm^2 (600 cm^2) of packaging). Calculating to this model can give misleading results if the pack has a high printed surface area and the weight of packaged goods is small. For example, a typical cereal box containing 500g of foodstuff may be supplied in a package that has a surface area of 2000 cm^2, i.e. half the weight in the EU model, and more than three times the area. The migration risk is therefore a factor of around six times higher than if calculated using the standard model. This could mean that a package construction previously determined as compliant may no longer conform to regulations as specific migration limits are exceeded. Since every packaging scenario is different, risk assessment for each is necessary to produce packaging with certainty.



Migration cells for Tenax®

Apart from migration, what else do I need to consider?

Although control of migration is one of the most critical aspects of producing compliant packaging, there are other important requirements needed for compliance. Transfer of substances from the packaging must not cause a deterioration in the organoleptic characteristics of the packaged foodstuff (affecting odour and taint/taste). The manufacture of the packaging must be adequately controlled to ensure sufficient quality and repeatability so that compliant packaging is produced, as part of Good Manufacturing Practice (GMP). In addition, there must be traceability of materials in the supply chain to facilitate control in cases of contamination, adulteration or defect, and product recall if necessary. Appropriate documentation must be kept, and passed along the supply chain to communicate suitability, use limitations and compliance work (for example in a Declaration of Compliance); labelling to indicate food contact use may also be required.

According to Good Manufacturing Practice (GMP), it is the responsibility of the packaging designer, the printer/converter that manufactures the packaging and the distributor of the product to ensure selection of appropriate materials for the end use of the packaging and that the packaging produced meets the requirements of the regulations. The printer/converter that applies the inks and coatings is responsible for the process of manufacture in order to produce compliant packaging. The ink and/or coating maker is obliged to formulate packaging inks so as to avoid transfer to the food contact surface through set-off or through migration. Once the capability for production of compliant packaging has been established during the design and material selection processes, and commercial production has begun, the printed material should be revalidated under normal production conditions and periodic monitoring conducted through migration testing following a planned sampling process.

Sun Chemical subscribes to the position that only migration compliant inks and coatings are recommended for primary food packaging applications, unless migration levels are proven to be compliant. Ink and coating makers are unable to take any responsibility for the use of non-migration compliant products in such applications. Further, ink and coating manufacturers cannot guarantee compliance of inks and coatings in specific applications due to the large number of variables in the pack design, printing and converting processes, overwhich they have no control. Sun Chemical will supply a Statement of Composition (SoC) for packaging inks providing details of potentially migrating substances, their levels in the print and applicable Specific Migration Limits (SMLs) or other restrictions, to assist convertor assessment of the risk and compliance of their product.

A partner who transforms with you.

Today's environment requires more than change. It demands transformation — and a partner who's willing to transform with you. Sun Chemical, a member of the DIC group, is a leading producer of packaging and graphic solutions, color and display technologies, functional products, electronic materials, and products for the automotive and healthcare industries. Together with DIC, Sun Chemical is continuously working to promote and develop sustainable solutions to exceed customer expectations and better the world around us. With combined annual sales of more than $8.5 billion and 22,000+ employees worldwide, the DIC Group companies support a diverse collection of global customers. As you move forward into a world of stiffer competition, faster turnarounds, more complex demands and sustainable products, count on Sun Chemical to be your partner.

working for you.

Sun Chemical
www. sunchemical.com | globalmarketing@sunchemical.com

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