

Isopropyl thioxanthone (ITX) and food packaging inks

Introduction

Following the publication of the EU's RASFF (Rapid Alert System for Food and Feed) for Week 37 (2005), EuPIA members have received a number of enquiries regarding the presence of ITX in inks and varnishes intended for food packaging. The RASFF alert warns that ITX has been found in milk for babies, having migrated from the packaging.

Summary

As a brief summary of the full situation report below, it can be noted that ITX has not been found to be genotoxic, and can continue to be used for food packaging; however, baby milk is a special case which may require reconsideration of the packaging construction.

Food Simulants and Migration Aspects

The risk from contamination of baby milk is particularly difficult to assess from the toxicological perspective. None of the usual assumptions about exposures, migration limits, tolerable daily intakes, etc, apply. It is clearly stated in the guidance for deriving acceptable daily intakes, for example, that such limits do not apply to young infants below the age of 3 months. This is because the metabolic processes and enzyme activity are still developing at that age, and also because the dietary intake is completely different. In view of these problems and uncertainties in undertaking a risk assessment for baby milk contamination, and also because of the emotive reaction to such findings, EuPIA members acknowledge that, despite the fact that no current regulations set particular provisions for infant foods, any detectable contamination of baby milk is likely to be perceived by experts as unacceptable.

This unfortunate situation has occurred despite good practices and control measures being employed within the packaging supply chain. Currently recommended methods for assessing migration from food packaging do not appear to adequately represent the special nature of milk (aqueous emulsion of fatty droplets). EU legislation and guidance for food contact materials specifies that Simulant A (distilled water) is the approved food simulant for migration testing when milk is the packaged foodstuff (surprisingly, there is no measure specifically for baby milk). When the packaging was tested using distilled water the migration was found to be negligible. When tested with more powerful simulants, such as 50% or 95% ethanol or modified polyphenyleneoxide ("Tenax®"), significantly more migration is observed. The latest thinking is that milk behaves less like water (despite its high water content), and rather more like the alcoholic simulants (because the migrants accumulate in the fatty phase of the emulsion).

There are no thresholds specified for migrating substances that have not been individually regulated in specific provisions, such as those for plastics in contact with foodstuffs. In addition, there are no regulations or measures relating to printing inks or migration from printed images, other than the general food safety requirement of Article 3 of the Food Contact Materials Framework Regulation (EC) No 1935/2004. Compliance with this requirement can be demonstrated by providing evidence that migrants do not endanger human health. This can be done by ensuring that the migration or exposure is below levels regarded as acceptable, in common with all other substances present in food contact materials and articles.

ITX in Food Packaging Inks

ITX is an important photoinitiator which is widely used in UV curing inks, with a long history of use. It has an essential role ensuring adequate through-cure and adhesion properties, particularly in dark pigmented inks.

ITX is not listed in the Synoptic Document, nor has it been assessed by the Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) Panel of the European Food Safety Authority (EFSA), or the former Scientific Committee on Food (SCF), since it is not used as a component in the manufacture of food contact plastic. Consequently, there are no expert opinions as to what constitutes a tolerable daily intake (TDI) or a specific migration limit (SML).

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In the absence of an expert consensus as to an acceptable level of migration, EuPIA members have followed the guidance issued by the AFC, SCF and EFSA experts regarding approvals of components used in materials intended for direct contact with food. ITX has been subject to a range of mutagenicity tests, covering both *in-vitro* and *in-vivo* assays in accordance with the latest OECD (Organisation for Economic Co-operation & Development) test protocols and GLP (Good Laboratory Practice).

The conclusion from these studies is that ITX is not genotoxic.

Since ITX is not genotoxic, a limit corresponding to 0.05 mg/kg food (i.e. 50 ppb), adjusted for any applicable food-type reduction factors, would be acceptable under the EFSA criteria set for food contact materials. Although migration may exceed this value, in this case, we recommend refinement of the compliance assessment be carried out in the future. Unfortunately, chronic toxicity data which might allow the derivation of the NOAEL (No Observed Adverse Effect Level) and a higher migration limit is not available for ITX. Depending on the future evolution of the regulations and EFSA assessment criteria, refinement of the exposure may be necessary to demonstrate that the application is acceptable.

UV printed packaging represents a minor share of the market for primary food packaging, at around 5% of the total. This means that application of the current EU model, which considers that all of the 1kg daily food intake is packaged in the affected packaging, results in a substantial overestimation of the actual exposure.

Consequently, it is considered that current UV curing inks and varnishes which contain ITX still enable the converter to print compliant food packaging.

It must be borne in mind that, in the light of possible future evolution in the understanding of the practical criteria for verifications of printed packaging, the packaging supplier and the filler may want to consider new aspects.

Obviously, the above-mentioned criteria for migration, risk, exposure and compliance assessments apply for all food packaging printed with any printing ink technology and/or printing technique.

As pointed out, the special nature of milk is at present underestimated when testing migration. We expect that the European Commission and the European Food Safety Authority (EFSA) will address this and issue revised guidance for milk simulants. In the meantime, we advise all those involved in the packaging of milk and milk products to take note of this finding and introduce appropriate measures to ensure compliance with the legislative requirements.

Conclusion

- **ITX is not genotoxic.**
- **UV curing inks and varnishes containing ITX can continue to be used for food packaging.**
- **Current models to demonstrate compliance with Art. 3 of Framework Regulation (EC) No 1935/2004 overestimate the exposure of the adult consumer to ITX.**
- **Although there are no thresholds specified by regulation, migration corresponding to corrected values not exceeding 0.05 mg/kg food (50 ppb) is acceptable**
- **Values above this need future refinements of compliance assessment criteria.**
- **Packagers of milk should be aware that the currently applicable assessment methods for milk products (i.e. the use of distilled water as the food simulant) underestimate the special nature of these products, and baby milk in particular.**
- **Where baby milk is being packed, careful consideration with regard to the design of the finished packaging needs to be undertaken.**