

Opinion on Isopropyl ThioXanthone (ITX) in food packaging inks

(Updated 2005-12-15)

EuPIA, as the Trade Association of the printing ink manufacturers in Europe, hereby informs its members, as well as the users of inks and related products, in regard to the situation on ITX as of 15th December 2005.

Introduction

EuPIA has issued on 2005-09-27 a first statement on ITX and food packaging inks. Since that date, there have been further publications of a number of alerts in Rapid Alert System for Food and Feed; this was done by the Commission on the basis of the precautionary principle as more information became available. As a result of all this activity, EuPIA issued a first update on 2005-12-05. Since the Standing Committee on the Food Chain and Animal Health of the European Commission as well as the European Food Safety Agency (EFSA) have recently published more information, EuPIA is issuing this second update to replace the previous publications.

The details on which the statement is based can be found below.

Summary

Current situation

- Converters and packaging fillers should be aware that the **currently specified food simulants** for milk, juices and other aqueous foods (simulant A –distilled water; simulant B - 3% acetic acid in water; simulant C – 10% ethanol in water) **are not always representative** for these foods, and can show lower migration values in the simulant tests than in the actual packaged food.
- The Standing Committee on the Food Chain and Animal Health of the European Commission made public its conclusions of the meeting that took place on 30th November to assess the situation with respect to the presence of ITX in milk for babies and other products. In the conclusions, the Standing Committee states: *“On the basis of the knowledge available today, the Standing Committee agreed that there is **no need to take any measures at EU level such as withdrawal of the concerned products from the market**”.*
- In view of the level of public concern, EFSA’s Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC), adopted, on the 7th December, well ahead of the originally announced schedule, its final opinion on ITX. EFSA made, on the 9th December, the following statement in the related press release, entitled *“ITX considered of low health concern”*: *“EFSA advises that the presence of ITX in foods, whilst undesirable, does not give cause for health concern at the levels reported. This confirms previous advice published by EFSA on 24th November 2005”.* In their recent journal, EFSA are stating furthermore: *“In conclusion, the existing in vivo genotoxicity studies do not indicate a genotoxic potential for ITX”.*
- The EU Commission published, on 13th December, the following statement: *“To avoid similar contamination incidents, the Commission will propose a measure detailing the requirements for good manufacturing practice which the packaging industry should apply. This measure will be proposed to the Member States as an implementing measure of the regulation on food contact materials”.*
- Although there are no thresholds specified by regulation, according to the EFSA “Note for Guidance for petitioners presenting an application for the safety assessment of a substance to be used in food contact materials prior to its authorisation” and on the basis of currently available toxicological data, migration corresponding to corrected values not exceeding 0.05 mg/kg food (50 ppb) is an acceptable threshold.

Guidance on the use of ITX

- Under the principles of the Framework Regulation (EC) No.1935/2004, inks and related products containing ITX can continue to be used on food packaging, provided that all measures are taken to minimise its migration, having regard to the higher exposure of infants and young children, in such a way that the level of dietary exposure does not endanger human health.
- Considering the announcement of the EU Commission of 13th December, and also the AFC Panel opinion of 7th December, EuPIA members recommend further evaluation of specific packaged products depending on final consumer applications.

ITX in inks for Food Packaging

ITX is an important photo-initiator widely used in UV curing inks. It has an essential role in ensuring adequate through-cure and adhesion, particularly in dark pigmented inks.

In the current situation with ITX, ink-manufacturers, in co-operation with other members of the supply chain, have taken measures to ensure that the migration potential of their UV inks in the particular applications will meet the required levels.

The operating principles of the food control system

Regulation (EC) No 178/2002, laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, entitles national food authorities to take provisional measures invoking the precautionary principle (Article 7(1): *In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment*). However, Article 7(2) stipulates that such measures “*shall be proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community, regard being had to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration. ...*”

Consequently, provisional measures by national authorities have to be commensurate in balancing the risk for the consumer against the potential restriction to trade and the technical and economic feasibility.

Migration and Food Simulants

Extensive analytical work done since the first finding of ITX in baby milk has revealed the following new scientific evidence:

- Currently recommended methods for assessing migration from food packaging do not 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. When the packaging was tested, in the past, using both distilled water and 10% ethanol, the migration was found to be negligible. When tested with more powerful simulants, such as 50% or 95% ethanol or modified polyphenyleneoxide (“Tenax®”), significantly elevated migration is observed. Evidently 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).
- EFSA’s AFC Panel reported, in its Opinion of 7th December, analogous evidence for under-assessment regarding migration into foodstuffs other than baby milk and milk products. In particular, cloudy fruit juices also behave like alcoholic simulants.

ITX and Food Packaging Legislation

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.

There are no thresholds specified for migrating substances such as ITX that have not been individually regulated in specific provisions, such as those for plastics in contact with foodstuffs.

Considering the results of a range of mutagenicity tests with 2-Isopropylthioxanthone, covering both *in-vitro* and *in-vivo* assays in accordance with the latest OECD (Organisation for Economic Co-operation & Development) test protocols, EFSA's AFC Panel concluded that, "*In conclusion, the existing in vivo genotoxicity studies do not indicate a genotoxic potential for ITX*".

Since EFSA's AFC Panel did not specify a migration limit for ITX, EuPIA members continue to recommend following the guidance issued by the EFSA experts regarding approvals of components used in materials intended for direct contact with food.

A migration limit corresponding to the extent of 0.05 mg/kg food (i.e. 50 ppb) is an acceptable threshold for substances with no genotoxic potential. In the event that the migration of ITX exceeds 50 ppb, the end use application, the nature and the extent of the exposure should be taken into consideration to demonstrate that the application is acceptable. In fact, EFSA's AFC Panel made, in its opinion of the 7th December, certain considerations with regard to the exposure of consumer groups to ITX at the levels found. The AFC Panel indicated the following conservative assumptions for exposure figures for ITX:

- infants fed exclusively with 1.06 liters of liquid infant formulae packed in cartons with UV-cured inks: 43 µg/kg bw/day (3-month infant weighing 6.1 kg)
- young children consuming 50% of his daily intake of 2 kg as food and beverages packed in UV-printed packages: 23 µg/kg bw/day (1.5 year child weighed 11 kg, assuming conservatively that his consumption is only milk)
- adult consuming 50% of his intake of 3 kg as food and beverages packaged in UV-printed cartons: 6µg/kg bw/day (weight 60 kg).

It should be noted that the UV printed packaging sector represents approximately 5% of the total primary food packaging market. This is significantly lower than the share of UV printed food packaging assumed by EFSA, indicating that the exposure was overestimated. This provides an increased margin of safety for the average adult consumer.

Consequently, and in view of the conclusions of the Standing Committee (30th November) and the EFSA press release (9th December), it is considered that current UV curing inks and varnishes which contain ITX can still enable the converter to print compliant food packaging.

Migration and exposure depend on a number of factors other than the ink formula, such as the actual printing conditions, the design and size of the packaging and the nature and the consumer category of the packed food.

Accordingly, verification as to the level of any migration is indispensable. This has to be done not just by the ink manufacturer who is responsible for the ink formula, but also by the responsible business operators, the converter and the packer, preferably with analytical testing on the final printed packaging. This verification shall take place with the advice from, and in close cooperation with, the ink manufacturer. It must be remembered that final responsibility lies with the person placing the package on the market.

Printing ink manufacturers are committed to work with converters on meeting migration requirements.

According to the EuPIA Guideline on Food Packaging Inks, the cooperation between ink manufacturer and converter is managed by requirement specifications, e.g. by information about the substrates, type of food packed, printing and converting process parameters, storage and treatment conditions, and end use application.

EuPIA and its members will continue to respond to new relevant evidence of migration properties of printed packaging, of migration behaviour of foodstuffs, and will continue to develop and offer adapted products to converters.

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