

# RESEARCH PAPER

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## **Comparing the Migration of Genotoxic Impurities in Colorants to Their Total Extracted Content**

**An Analysis of Plastic Additive Risk in Food-Contact Applications**

**Colour Synthesis Solutions, LLC**

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## 1. Abstract

Research was conducted to compare the variety and quantity of a wide array of degradation products of common food-contact dyes – Solvent Blue 104 (CAS No 116-75-6) and Solvent Yellow 114 (CAS No 17772-51-9) – in both the observed total extracted value and that which migrated under conditions of use typically encountered in food-contact applications. Solvent Blue 104 is often used as a plastic additive for the coloration of drinking water bottle jugs and bottles – articles that are typically exposed to conditions of use no greater than room temperature (recommended to be tested at 40 degrees C per FDA guidance) and Solvent Yellow 114 is an important element in creating trichromatic blends for amber bottles. Polyethylene Terephthalate (PET) was the resin of focus as it represents a dramatic percentage of food-contact materials and articles that are coloured throughout the world. Further in previous, related investigations into the behaviour of the migration of degradation products from dyes, it has been established that often the worst-case scenario for migration occurs from engineering grade PET, devoid of copolymers and crosslinkers. Should migration of small, organic molecules like primary aromatic amines occur, it will do so most readily from PET that is not designed for hot-fill applications or is otherwise more amorphous than crystalline.

Goals of this work include the creation of baseline expectations for business operators who are either manufacturing or purchasing colorants as additives for plastics applications of the performance of these materials in terms of their likelihood to fail compliance with European plastics regulations. It is of premier importance to know the levels of impurities that are appreciably genotoxic or cannot be ruled out as genotoxic within the list of ingredients comprising an additives package for plastic materials and articles expected to come into contact with food. However, it is functionally more important to know whether under foreseeable conditions of use for which a statement of compliance shall be issued, that those impurities will indeed migrate. The work in this paper directly compares the total extracted content of 55 PAA in samples of dye extracted with a customized ETAD method to the same dyes compounded into engineering grade PET, which underwent typical conditions of use to show that what is totally possible does not necessarily migrate out. This information is quite useful to business operators who must make difficult decisions and shoulder liability for issuing declarations of compliance for materials that inherently contain genotoxic products of degradation. By knowing what is present in the additives as they are purchased as well as the degree to which they are expected to migrate in worst-case scenarios, the better informed a business is when making the decisions to place products on the market. Until such time as the United States issues revised legislation or chemistry recommendations tantamount to (EU) No 2020/1245, the latter shall serve at the bar to which colorants and all plastics additives are held, worldwide.