

## Colourants In Cosmetics – A Regulatory And Safety Review

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### Abstract

Colouring agents (colourants) are probably one of the most popular, single ingredients in cosmetic products. They have two obvious appeals. The first is to the consumer where they provide a way in which a person can change his or her appearance. The second appeal is to the manufacturer/supplier, as colouring agents make the product instantly noticeable and desirable for purchase. Due to the diversity and variation in purity of colourants, robust legislation exists in the European Union (EU), Japan and the United States of America (USA) to regulate their use in cosmetic products. However, views on the safety of the same colourant may vary between countries. How do these variations in regulations affect safety assessments of cosmetic products? Can there be harmonisation of these various systems? In this review, we will examine the global need for harmonisation of colourants and whether the current systems can serve as model for safety assessment of colourants in other consumer products.

### Introduction

The regulation governing the safe use of cosmetic products in the USA (U.S. Food, Drug Administration, FDA Title 21 CFR) is less specific than for food and drugs (Casterton, 2006)<sup>1</sup> and also less specific than in the EU. In the USA, “cosmetic products and ingredients are not subject to FDA pre-market approval” (www.cfsan.fda.gov). This is in direct contrast to the EU market whereby ingredients, colourants and the final products are subject to detailed regulatory control in the form of the EU Council Directive 76/768/EEC and its amendments, prior to sale to the general public. However unlike general ingredients, in the USA colourants particularly used in cosmetic, drug and food products are robustly regulated; this is illustrated from data extracted from a compiled list of cosmetic colourants used

in the EU (Annex IV), Japan and the USA (CTFA International Color Handbook, 2003)<sup>2</sup>. The data indicate that fewer colourants are permitted in cosmetic products sold in the USA than in either the EU or in Japan (Figure 1).

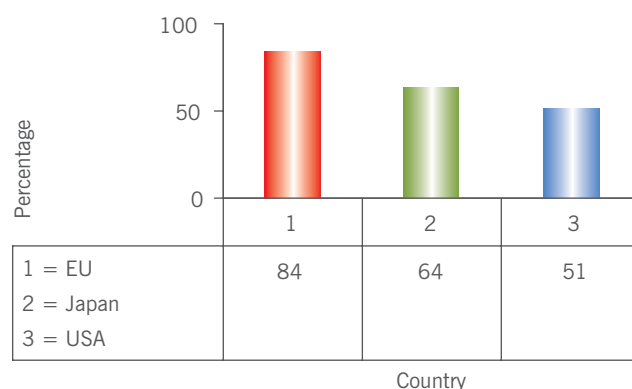


Figure 1: Approved Cosmetic Colourants

Figure 1 shows that of the combined total of 213 colourants (listed by Colour Index Number) available for use in leave-on and rinse-off cosmetic products by the three different regulatory bodies (EU, Japan and the USA), just over 50% are allowed in the USA as colour additives, approximately 64% by Japan and 84% by the EU. Not surprisingly, the reverse is true for colourants not approved or prohibited for use in cosmetic products (Figure 2): in descending order, USA (58%), Japan (35%) and EU (16%). Thus, of all the listed colourants, a disproportionate number are specifically not permitted in the USA cosmetic market, followed by Japan and with the least non-approved or prohibited colourants in the EU. Four more colourants were deleted from the EU regulated list and about two new ones added but these were not considered a necessary contributory factor to the illustrative point in question. Furthermore, compared to the EU and US, a considerable number of what they consider colourants or colour additives are listed as ingredients by Japan (Figure 3). What is therefore a colourant and how is it different from an ingredient?