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Review

Carcinogenicity of azo colorants: influence of solubility and bioavailability

Dedicated to the late Christian Hodel

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Abstract

In the past, azo colorants based on benzidine, 3,3'-dichlorobenzidine, 3,3'-dimethylbenzidine (*o*-tolidine), and 3,3'-dimethoxybenzidine (*o*-dianisidine) have been synthesized in large amounts and numbers. Studies in exposed workers have demonstrated that the azoreduction of benzidine-based dyes occurs in man. The metabolic conversion of benzidine-, 3,3'-dimethylbenzidine- and 3,3'-dimethoxybenzidine-based dyes to their (carcinogenic) amine precursors *in vivo* is a general phenomenon that must be considered for each member of this class of chemicals. Several epidemiological studies have demonstrated that the use of the benzidine-based dyes has caused bladder cancer in humans. However, in contrast to water-soluble dyes, the question of biological azoreduction of (practically insoluble) pigments has been a matter of discussion. As a majority of azo pigments are based on 3,3'-dichlorobenzidine, much of the available experimental data are focused on this group. Long-term animal carcinogenicity studies performed with pigments based on 3,3'-dichlorobenzidine did not show a carcinogenic effect. The absence of a genotoxic effect has been supported by mutagenicity studies with the 3,3'-dichlorobenzidine-based Pigment Yellow 12. Studies in which azo pigments based on 3,3'-dichlorobenzidine had been orally administered to rats, hamsters, rabbits and monkeys could generally not detect significant amounts of 3,3'-dichlorobenzidine in the urine. It, therefore, appears well established that the aromatic amine components from azo pigments based on 3,3'-dichlorobenzidine are practically not bioavailable. Hence, it is very unlikely that occupational exposure to insoluble azo pigments would be associated with a substantial risk of (bladder) cancer in man. According to current EU regulations, azo dyes based on benzidine, 3,3'-dimethoxybenzidine and 3,3'-dimethylbenzidine have been classified as

carcinogens of category 2 as "substances which should be regarded as if they are carcinogenic to man". This is not the case for 3,3'-dichlorobenzidine-based azo pigments.

Keywords

Azo colorants; Azo dyes; Azo pigments; 3,3'-Dichlorobenzidine; Bioavailability; Carcinogenicity

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