C.I. Acid Orange 3

5[(2,4-dinitrophenyl)amino]-2-(phenylamine)-benzenesulfonic acid, monosodium salt

C. I. Acid Orange 3, a dinitrodiphenylamine derivative, is a dye used in semi-permanent hair coloring products and for dying textiles. Manufacturers, consumers and beauty salon workers are exposed.

C. I. Acid Orange 3 passed the animal data screen, underwent a preliminary toxicological evaluation, and is being brought to the Carcinogen Identification Committee for consultation. This is a compilation of the relevant studies identified during the preliminary toxicological evaluation.

Epidemiological data

No cancer epidemiology studies were identified.

Animal carcinogenicity studies

- 103-week gavage studies
 - Male and female F344/N rats: NTP (1988)
 - Increase in rare renal transitional cell carcinomas of renal pelvis in females
 - No treatment-related tumor findings in males
 - Male and female B6C3F₁ mice: NTP (1988)
 - No treatment-related tumor findings

Other relevant data

- Genotoxicity
 - Review of mutagenicity studies in Salmonella typhimurium, with and without exogenous metabolic system: NTP (1988) and Zeiger *et al.* (1988), as cited in IARC (1993)
 - Positive in some Salmonella strains, negative in one strain
- Structure activity considerations
 - C.I. Acid Orange 3 is a nitroaromatic compound with broad structural similarity to Proposition 65 carcinogens: 2,4-dinitrotoluene, *o*-nitroanisole, nitrobenzene and *o*-nitrotoluene.

Review

• IARC (1993)

References¹

International Agency for Research on Cancer (IARC, 1993). IARC Monographs on the Evaluation of Carcinogenic Risks to Humans. Occupational exposures of hairdressers and barbers and personal use of hair colourants; some hair dyes; cosmetic colourants, industrial dyestuffs and aromatic amines. Volume 57, IARC, Lyon, France, Pp 121-127.

National Toxicology Program (NTP, 1988). *Toxicological and Carcinogenesis Studies of CI Acid Orange 3 in F344/N Rats and B6C3F1 Mice (Gavage Studies)*, NTP TR 335, NIH Publication No. 89-2591, National Institutes of Health.

¹ Excerpts or the complete publication have been provided to members of the Carcinogen Identification Committee, in the order in which they are discussed in this document.