

A carcinogenicity study of sucralose in the CD-1 mouse.

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The potential carcinogenicity of sucralose was evaluated by feeding groups of 52 male and 52 female CD-1 mice a diet containing sucralose at 0.3% (3000 ppm), 1.0% (10,000 ppm) or 3.0% (30,000 ppm) for 104 weeks. A group of 72 male and 72 female mice received diet without sucralose and served as controls. Week 1 achieved doses ranging from 543 to 5870mg/kg body weight/day in the low-dose males and high-dose females, respectively. Sucralose had no adverse effect on survival.

No significant changes attributable to sucralose were found in the clinical condition or behaviour of the mice. Organ weights and the gross appearance of tissues were unaffected by treatment. The mean erythrocyte counts of females receiving the highest dietary concentration were slightly, but statistically significantly, lower than those of the controls after 104 weeks of treatment. Group mean body weight gain at the highest dietary concentration of sucralose was significantly less than that of the control in mice of both sexes.

Food consumption, after correction for sucralose content, was lower for female mice, but not statistically significant. Water consumption for male mice receiving the highest dietary concentration was approximately 9% higher than that of the controls. There were statistically significant increases in the incidence of several non-neoplastic findings, but these were not considered to be related to sucralose administration. Treatment with sucralose did not increase the incidence of any tumour or influence the types of tumours observed. It was concluded that sucralose is not carcinogenic in CD-1 mice.

The body weight gain and erythrocyte observations at the 3.0% dietary level were of limited biological significance as they were not accompanied by any histopathologic finding and had no impact on survival. The remaining dose levels were judged to have no effects.