

Acute and subchronic toxicity of sucralose.

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The toxicity of sucralose has been evaluated in acute and subchronic toxicity studies. Acute oral toxicity studies in male and female mice and male rats documented no deaths or treatment-related signs at doses of 16g/kg for mice and 10g/kg for rats. Sucralose was administered to male and female rats for 4 and 8 weeks at dietary concentrations of 1.0, 2.5 or 5.0%. Achieved dose ranges (mg/kg/day) for the respective dietary level were 737-1287, 1865-3218 and 2794-6406.

There were no toxicologically significant effects observed at the 1.0% or 2.5% dietary levels. However, decreases in food consumption, body weight gain and selected organ weights and ratios as well as splenic and thymic histopathologic changes occurred in rats administered 5.0% for 4 or 8 weeks.

A gavage study wherein doses of 0, 750, 1500 or 3000mg/kg/day were administered to male and female rats for 26 weeks investigated further the observations from the dietary study as well as general subchronic toxicity.

The gavage study documented no sucralose-related toxicity. These results implicate the reduced palatability and digestibility of diets containing high concentrations of sucralose seen in the diet study as the cause for the decreased food consumption and other accompanying alterations. Dose selection for chronic toxicity studies in rats took into consideration the effect of high concentrations of sucralose on digestion and food consumption and the limitations that would be imposed on subsequent studies.

In male and female dogs, no sucralose-related adverse effects were observed following the dietary administration of 0.3, 1.0 or 3.0% for 12 months achieving doses of approximately 90, 300 and 900mg/kg/day respectively. These studies establish that sucralose is non-toxic in rodents following acute oral administration. The rat no-observed-adverse-effect level ranged between 2.5 and 5.0% following subchronic dietary administration. A 3.0% dietary concentration equivalent to a dose of 900mg/kg/day produced no adverse effects in beagle dogs when fed for 12 months.