

Safety of Long-term Large Doses of Aspartame

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Safety of long-term administration of 75 mg/kg of aspartame per day was evaluated with the use of a randomized, doubleblind, placebo-controlled, parallel-group design in 108 male and female volunteers aged 18 to 62 years. Subjects received either aspartame or placebo in capsule form three times daily for 24 weeks. No persistent changes over time were noted in either group in vital signs; body weight; results of standard laboratory tests; fasting blood levels of aspartame's constituent amino acids (aspartic acid and phenylalanine), other amino acids, and methanol; or blood formate levels and 24-hour urinary excretion of formate. There also were no statistically significant differences between groups in the number of subjects experiencing symptoms or in the number of symptoms per subject. These results further document the safety of the long-term consumption of aspartame at doses equivalent to the amount of aspartame in approximately 10 L of beverage per day.

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