





The Metabolic Fate and Safety of Stevia Leaf Extract

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Berna Magnuson is Vice President of Health Science Consultants, Inc. in Mississauga, Canada. As a scientific and regulatory consultant for over ten years, she works with clients to address challenges in safety assessment and regulatory approval of novel foods, food and beverage ingredients, and dietary supplements. As a food scientist, she worked in the food industry in quality assurance and product development before undertaking graduate training in food toxicology and cancer research. Dr. Magnuson was a full-time professor for over 15 years, at the Universities of Idaho and Maryland, conducting research and teaching food, nutrition and toxicology courses. Dr. Magnuson then returned to Canada to do food safety and regulatory consulting and teach food regulatory courses at the University of Toronto. As a consultant, she provides expertise in food regulations, nutrition and toxicology to food, beverage, and dietary supplement manufacturers and ingredient industries, as well as health professional and consumer associations. Dr. Magnuson has extensive experience and expertise in food additive safety, including low calorie sweeteners, and serves as an expert advisor and speaker on this topic around the world. In addition to confidential client reports and regulatory submissions, she has published over 60 peer-reviewed articles, book chapters, and professional articles, serves on the editorial board of two journals, and is an active member of various professional associations. Berna obtained a BSc (Honors) in Food Science and Nutrition, and an MSc in Toxicology from the University of Saskatchewan, and PhD in Nutritional Sciences from the University of Manitoba in Canada. She was a Canadian Health Services Utilization and Research Commission Postdoctoral Fellow at the Saskatchewan Cancer Research Centre.

ABSTRACT

Stevia leaf extract that has been purified to contain a minimum of 95% steviol glycosides (SG) is approved for use as a low calorie sweetener in foods and beverages in many international jurisdictions. The number and type of steviol glycosides that are approved for use in a stevia leaf extract sweetener continues to grow with developments in isolation, extraction and modification methods, leading to improvements in taste. Examples include approval of use of Reb M and enzyme-modified SG. The safety of use of SG is based on years of research and testing, including extensive evaluation of the absorption, distribution, metabolism and excretion of SG illustrating that all SG have one common metabolite, steviol, that is absorbed. This has been demonstrated in both animal studies and human clinical studies and is the basis for establishing an ADI as "steviol equivalents". The safety studies conducted on SG have demonstrated no effect on genetic material or on development of cancer. Administration of high daily doses of SG to rodents for up to two years, during growth and development as well as during pregnancy and lactation in multigeneration studies have demonstrated no adverse effect of long-term use throughout life stages. SG also have little potential to induce allergies. Human studies have also been conducted to confirm animal studies that chronic consumption of steviol glycoside extract sweetener are well tolerated and have no pharmacological or adverse effects. This presentation will provide an overview of the metabolic fate of SGs and a summary of safety studies conducted that support the safe of use of purified stevia leaf extract as a low calorie sweetener.