This is a provisional English translation of an excerpt from the original full report.

Risk Assessment Report

Advantame (Food Additives)

Food Safety Commission of Japan (FSCJ)

July 2013

ABSTRACT

The FSCJ conducted a risk assessment of "advantame" (CAS number: 714229-20-6), a food additive used as a sweetener, using results from various studies.
The results used for the assessment include data on toxicokinetics, genotoxicity, acute toxicity, repeated dose toxicity, carcinogenicity, reproductive and developmental toxicity, allergenicity and general pharmacology in experimental animals and human data on advantame as the test substance.

FSCJ reviewed toxicokinetics of advantame in experimental animals, its general pharmacology and also data on humans, and concluded that these data showed no matters of concern for food safety.

FSCJ concluded that advantame and its degraded-products are of no concern in terms of their genotoxicity.
FSCJ reviewed the acute toxicity, repeated dose toxicity, carcinogenicity, reproductive and developmental toxicity and allergenicity of advantame. In a prenatal developmental toxicity study in rabbits, dams administered advantame exhibited digestive disorders accompanied by deterioration of general conditions at doses of 1,000 mg/kg bw/day or higher. FSCJ attributed this effect to the administration of advantame, and regarded 500 mg/kg bw/day (a dose lower than that causing the above-mentioned effect) as the minimum NOAEL of advantame. In addition, FSCJ concluded on the basis of its review that advantame showed no carcinogenicity.

Taking the observed toxicological effects and the estimated intake of the additive "advantame" (3.57 mg/person/day (0.0714 mg/kg bw/day)) after its approval in Japan into account, FSCJ considered that it is necessary to specify an ADI for the additive "advantame". FSCJ specified the ADI of 5.0 mg/kg bw/day, based on the NOAEL in the prenatal developmental toxicity study in rabbits (500 mg/kg bw/day) and applying a safety factor of 100.