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

Risk Assessment Report

β -apo-8'-carotenal

(Food Additives)

Food Safety Commission of Japan (FSCJ)

November 2013

ABSTRACT

FSCJ conducted a risk assessment of an additive "β-apo-8'-carotenal" (used as a food coloring. CAS No. 1107-26-2 (as β-apo-8'-carotenal)) based on various studies.
The data used in the assessment were on: genotoxicity, repeated dose toxicity, carcinogenicity, reproductive and developmental toxicity, etc., of β-apo-8'-carotenal as the test substance.

Based on pharmacokinetics and general pharmacology data, FSCJ considered β-apo-8'-carotenal to be of no concern for food safety.

Also FSCJ concluded that β-apo-8'-carotenal has no genotoxicity relevant to human health.

FSCJ assessed test results on acute toxicity, repeated dose toxicity, carcinogenicity and reproductive and developmental toxicity of β-apo-8'-carotenal. In a repeated dose 90-day oral toxicity study in rats, eosinophilic droplets in the kidneys were observed in rats exposed to a dose of 10 mg/kg body weight/day. FSCJ considered that this result was attributed to β-apo-8'-carotenal dose, and concluded that 10 mg/kg body weight/day was the lowest observed adverse effect level (LOAEL) of β-apo-8'-carotenal. In addition, FSCJ concluded that β-apo-8'-carotenal has no carcinogenicity.

Based on the results of studies on human health, FSCJ concluded that there is no evidence of safety concerns of β-apo-8'-carotenal.
Taking into account the toxicological findings and the intake of an additive "β-apo-8'-carotenal" estimated as if its use is approved in Japan (0.36 mg/person/day (0.0072 mg/kg body weight/day), FSCJ considered that the acceptable daily intake (ADI) of the additive "β-apo-8'-carotenal" needed to be specified. The LOAEL of 10 mg/kg body weight/day in the repeated dose 90-day oral toxicity study in rats is judged to be appropriate as the basis of ADI. FSCJ adopted the safety factor of 200 (10 for species differences, 10 for individual differences and 2 for the facts that ADI is based on LOAEL and toxicological results were insignificant (eosinophilic droplets in the kidneys for females)). Thus dividing 10 mg/kg body weight/day by the overall safety factor of 200, FSCJ specified the ADI of the additive "β-apo-8'-carotenal" to be 0.05 mg/kg body weight/day.