

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

Risk Assessment Report

Triethyl citrate (Food Additives)

Food Safety Commission of Japan (FSCJ)
February 2015

ABSTRACT

FSCJ conducted a risk assessment of triethyl citrate (CAS No. 77-93-0, as triethyl citrate), an additive used as an emulsifier, stabilizer, and flavouring, based on results from various studies. The data used in the assessment include genotoxicity, acute toxicity, repeated dose toxicity, carcinogenicity, reproductive and developmental toxicities, and human data on triethyl citrate as the test substance.

FSCJ reviewed pharmacokinetics of triethyl citrate and concluded that the data showed no matters of concern for food safety.

Also FSCJ concluded that triethyl citrate has no genotoxicity relevant to human health.

FSCJ assessed test results on acute toxicity, repeated dose toxicity, carcinogenicity and reproductive and developmental toxicity, and human data on triethyl citrate. FSCJ regarded 2,000 mg/kg bw/day obtained at the highest dose level in two-year oral toxicity studies in rats as no-observed-adverse-effect level (NOAEL) of triethyl citrate. In addition, FSCJ concluded that triethyl citrate has no carcinogenicity.

The estimated daily intake of triethyl citrate would be 127 mg/person/day (2.3 mg/kg body weight/day) if its use is approved in Japan.

Taking the estimated intake into consideration, the assessed item is considered of no concern for food safety as long as used appropriately as an additive, and FSCJ concluded that it is not necessary to specify the acceptable daily intake (ADI) of the additive “triethyl citrate”.