

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

Risk Assessment Report Sodium stearoyl lactylate (Food Additive)

Food Safety Commission of Japan (FSCJ)
July 2008

Executive summary

The Food Safety Commission of Japan (FSCJ) conducted a risk assessment of sodium stearoyl lactylate e [CAS No. 25383-99-7], a food additive used as an emulsifier, using various test data.

The test results used for the assessment are related to the repeated-dose toxicity, carcinogenicity, reproductive and developmental toxicity and genotoxicity, etc. of sodium stearoyl lactylate and other stearoyl lactylates.

Although the toxicity test results of sodium stearoyl lactylate provided for the assessment were not complete, its comprehensive evaluation was considered possible by using the test data for calcium stearoyl lactylate, also referring to the test data for stearate and lactic acids as well.

Toxicological test results of sodium stearoyl lactylate, calcium stearoyl lactylate, and those of stearates and lactic acids as reference, showed no carcinogenicity, reproductive and developmental toxicity and genotoxicity .

The minimum value of NOAEL for sodium stearoyl lactylate is considered to be 4.0% (2,000 mg/kg body weight/day) based on the decrease in body weight gain and increase in relative liver weight observed in 1-month repeated-dose toxicity tests on rats. Hence, using a safety factor of 100, FSCJ specified the acceptable daily intake (ADI) for sodium stearoyl lactylate as 20 mg/kg body weight/day.