

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

Risk Assessment Report Calcium Sorbate (Food Additive)

Food Safety Commission of Japan (FSCJ)
November 2008

Executive summary

The Food Safety Commission of Japan (FSCJ) conducted a risk assessment of calcium sorbate [CAS No. 7492-55-9], a food additive used as a preservative, using various test results.

The test results used in the assessment are related to the repeated-dose toxicity, carcinogenicity, reproductive and developmental toxicity, genotoxicity, etc. of sorbic acids and/or sorbates.

Although the toxicity test results of calcium sorbate were not available, a comprehensive evaluation of sorbic acid and sorbates as a group was considered possible by using the test data for sorbic acid and sorbates other than calcium sorbate.

Toxicological test results of sorbic acid and its salts showed no carcinogenicity. No particular toxic effect which causes safety concern was noted with a dose range up to 5.0% in repeated-dose toxicity tests. Also, there seems to be no particular genotoxicity relevant to human health.

The minimum value of NOAEL for sorbic acid is considered to be 5.0% (2,500 mg/kg body weight/day). Hence, using a safety factor of 100, FSCJ specified the acceptable daily intake (ADI) of 25 mg/kg body weight/day in the form of sorbic acid for a group of calcium sorbate, sorbic acid and potassium sorbate, the last two of which are already approved for use in Japan.