

[Summary]

Assessment of the effect of food on health of "Calcium Silicate" (CAS number: 1344-95-2), a food additive used as anticaking agent, was performed by using various test data.

The data used for the assessment included those of repeated-dose toxicity, reproductive and developmental toxicity, genotoxicity and etc. on silicates, such as silicon dioxide, sodium silicate and aluminum silicate.

Although the toxicity test results submitted for Calcium Silicate were not exclusive, a comprehensive evaluation was considered possible using the test data for Silicon Dioxide, which has already been approved for use in Japan.

Study results showed no carcinogenicity, reproductive and developmental toxicity, or genotoxicity. In repeated-dose toxicity studies, no particular toxic effects that might cause safety concerns were noted.

Meanwhile, Silicon dioxide and Calcium Oxide, a composition of Calcium Silicate, have been used as food additives in Japan, and no particular safety problem has so far been indicated. JECFA made the evaluation to conclude that "ADI (Acceptable Daily Intake) was not specified" for silicon dioxide and silicates (including calcium silicate) in 1970.

Taken together, there appeared no safety concerns, when Calcium Silicate was appropriately used as a food additive, and it was thus concluded that no ADI needed to be specified.