

Evaluation Report of Food Additives "Calcium L-Ascorbate"

August, 2007

Food Safety Commission

[Summary]

Assessment of the effect of food on health of "Calcium L-Ascorbate" (CAS number: 5743-27-1, 5743-28-2), an food additive used as an antioxidant, and as nutritional supplement (vitamin C and calcium), was performed by using various test data.

The data used for the assessment included those of repeated-dose toxicity, carcinogenicity, reproductive and developmental toxicity, genotoxicity and etc., on calcium L-ascorbate and other L-ascorbates.

Although the toxicity test results submitted for Calcium L-Ascorbate were not exclusive, a comprehensive evaluation was considered possible using the test data for L-Ascorbates, which have already been approved for use in Japan.

Study results of calcium L-ascorbate and other L-ascorbates 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, L-Ascorbic Acid and other L-Ascorbic salts including Sodium L-Ascorbate 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 calcium L-ascorbate.

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