

Evaluation Report of Food Additives “Magnesium Hydroxide”

Nov, 2007

Food Safety Commission

[Summary]

Assessment of the effect of food on health of “Magnesium Hydroxide” (CAS number.: 1309-42-8), an food additive used as fortifying agent, pH adjusting agent and color stabilizer, 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 magnesium hydroxide and other magnesium salts.

Although the toxicity test results submitted for Magnesium Hydroxide were not exhaustive, a comprehensive evaluation was considered possible using the test data for magnesium chloride and other magnesium salts.

Study results of magnesium hydroxide and other magnesium salts including magnesium chloride, 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, Magnesium Chloride and other magnesium salts 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 magnesium salts including magnesium hydroxide.

Taken together, there appeared no safety concerns, when magnesium hydroxide was appropriately used as a food additive, and it was thus concluded that no ADI needed to be specified. However, higher sensitivity to magnesium and excessive intake of magnesium above the recommendation through foods have been indicated in children. So, appropriate measures including labeling with warning message should be taken for children including infants not to take magnesium excessively, when magnesium salts are used for nutritional fortifying purposes.