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Risk Assessment Report Magnesium silicate (Food Additive)

Food Safety Commission of Japan (FSCJ)
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Executive summary

Using various test results, the Food Safety Commission of Japan (FSCJ) conducted a risk assessment of magnesium silicate [CAS No. 1343-88-0 (as magnesium silicate)], a food additive used as an anticaking agent, filtering aid, and an agent to manufacture capsule or tablet-shaped food.

The study results used in the assessments are related to the repetitive dose toxicity, carcinogenicity, reproductive and developmental toxicity and genotoxicity studies of magnesium silicate and other substances.

In addition to the study results of this food additive, we also referred to the test results of other silicate compounds and magnesium salts, taking into account the findings of its *in vivo* kinetic.

Evaluating the results of safety studies of magnesium silicates, including magnesium trisilicate, as well as other silicate compounds and magnesium salts, indicated no carcinogenicity, reproductive or developmental toxicity, or genotoxicity.

The lowest no observed adverse effect level (NOAEL) obtained from the toxicity tests was 300 mg/kg body weight/day in 28-day repetitive dose toxicity studies in dogs, which is lower than the NOAELs of the referred silicate compounds and magnesium salts in the conversion of both silicon (Si) and magnesium (Mg).

Based on the value of 300 mg/kg body weight/day, the FSCJ determined the amount of daily intake (ADI) to be 0.3 mg/kg body weight/day, by applying the safety factor of 1,000 considering the short duration of the study.

Our determining the ADI of magnesium silicate as food additive in particular is not intended to restrict an additional intake of magnesium, which is necessary in the nutritional aspect, and of other additives such as silicate compounds or magnesium salts.

It is suggested that children are highly sensitive to magnesium, and that the amount of magnesium intake from food could exceed the recommended amounts in infants and children. Therefore, with respect to food to which magnesium salt is added for nutrient fortification purpose, appropriate measures, such as the labelling of warning notice, should be taken to avoid an excessive magnesium intake in infants and children.