

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

Risk Assessment Report

1-Methylnaphthalene (Food Additives)

Food Safety Commission of Japan (FSCJ)
May 2015

ABSTRACT

FSCJ conducted a risk assessment of 1-Methylnaphthalene (CAS No. 90-12-0), as an additive (flavoring), based on results from various studies.

The data used in the assessment include genotoxicity, repeated dose toxicity and carcinogenicity.

FSCJ considered that 1-methylnaphthalene has no apparent toxicity relevant to human health, at least at the dose range normally used for a flavor, on the basis of the results of the genotoxicity and repeated dose toxicity studies.

In 81-week chronic toxicity/carcinogenicity combined study, this additive exhibited a weak carcinogenicity in mouse lung. No pulmonary genotoxicity was detected, however, in the transgenic mice, suggesting that the observed weak carcinogenicity of this additive is not attributed to genotoxic mechanisms. In addition, the weak carcinogenicity observed in the lung of mice was suggested to be mice-specific. Therefore, FSCJ concluded that the threshold can be specified.

FSCJ recognized that the safety margin can be appropriately assessed based on the NOAEL of 2 mg/kg bw/day obtained in 90-days repeated dose toxicity test, in comparison with LOAEL obtained in 81-week chronic toxicity/carcinogenicity combined study in mice (as 71.6 mg/kg bw/day for the male, and 75.1 mg/kg bw/day for the female).

FSCJ confirmed that the additive (flavoring) was categorized into Structural class III, based on Method of safety assessment on internationally commonly used flavorings¹. The safety margin (110,000 ~ 1,660,000) exceeds 1,000 which is regarded as the appropriate safety margin for a 90-day repetitive dose toxicity study and also the predicted amount of intake (0.06~0.9 µg/person/day) are lower than the acceptable daily intake for a substance of Structural class III (90 µg/person/day).

Hence, FSCJ concluded that 1-methylnaphthalene, an additive (flavoring), has no concern relevant to human health as used for the purpose of flavoring food.

¹ Report of Working group on safety assessment method of flavorings, November 4, 2003