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

Risk Assessment Report

Dipotassium L-Tartrate and Metatartaric acid

(Food Additive)

Food Safety Commission of Japan (FSCJ)
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ABSTRACT

The FSCJ conducted a risk assessment of dipotassium L-tartrate (CAS No. 6100-19-2) and metatartaric acid (CAS No. 56959-20-7/39469-81-3), additives used as food manufacturing agents, based on results from various studies.

The data of the following studies were analyzed: toxicokinetics; genotoxicity; acute toxicity; repeated dose toxicity; carcinogenicity; reproductive and developmental toxicity; and scientific findings in human, etc. The test substances include tartaric acid and tartrate in addition to dipotassium L-tartrate and metatartaric acid.

Assuming that dipotassium L-tartrate and metatartaric acid would be absorbed as L-tartarate ions, the FSCJ determined the plausibility to conduct the extensive risk assessment of these additives as a group analyzing the overall data from studies on tartaric acid and tartrate substances (including some data on substances of unknown optical rotation and DL-tartaric acid).

The FSCJ observed the following facts:
- Dipotassium L-tartrate and metatartaric acid showed no genotoxicity relevant to human health ;
-Combined two-year repeated dose toxicity/carcinogenicity study on L-tartrate in rats showed no toxicity and carcinogenicity with the maximum dose (2,440 mg/kg bw/day for L-tartaric acid) ; and
-Developmental toxicity study in rats and mice showed no toxicity.

The FSCJ determined that to establish a NOAEL would not be possible from the data obtained in scientific findings in human.

The FSCJ identified a NOAEL of dipotassium L-tartrate acid to be 2,440 mg/kg bw per day.

The FSCJ estimated the daily intake of L-tartaric acid to be 239 mg/person per day (4.3 mg/kg bw per day), adding the estimated daily intake of dipotassium L-tartrate and metatartaric acid to the current intake of L-tartaric acid.

The FSCJ did not conduct advanced evaluation of the toxicokinetics and toxicity of potassium ion because no findings had been identified in the risk assessment of pottsium already conducted. However, taking the following

all facts into consideration, the FSCJ determined that potassium derived from dipotassium L-tartrate had no food safety concern as long as it is used appropriately as a food additive:

- Potassium is an ion widely distributed in human blood, urine and each organs;
- Target intake of potassium (2,600 ~ 3,000 and more mg/day for men/women of 18 years and over) is established; and
- The estimated daily intake of potassium derived from dipotassium L-tartrate (88mg for potassium) is very low (about 4 %) of its current daily intake (2,362 mg).

The FSCJ compared the above estimated daily intake of L-tartaric acid [239 mg/person per day (4.3 mg/kg bw per day) with the NOAEL (2,440 mg/kg bw per day)]. The FSCJ did not identify toxicity at the maximum in a two-year combined repeated dose/carcinogenicity study in rats. Meanwhile, adverse effects were observed in scientific findings in human at a dose above the range of intake with the appropriate use for an additive. Given these, the FSCJ concluded that a group ADI for dipotassium L-tartrate and metatartaric acid should be specified.

Consequently, the FSCJ established an ADI of 24 mg/kg bw per day (L-tartaric acid) for a group of additives, dipotassium L-tartrate and metatartaric acid, based on the NOAEL of 2,440 mg/kg bw per day (L-tartaric acid) obtained in a combined two-year repeated dose/carcinogenicity study in rats, applying a safety factor of 100 to the NOAEL.