

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

Risk Assessment Report

ピュアカム葉酸及びピュアカム葉酸MV
*Pyuakamu-yosan and Pyuakamu-yosan MV*¹
(A tablet-formed food containing folic acid)
(Food for specified health uses)

Food Safety Commission of Japan (FSCJ)
February 2016

ABSTRACT

FSCJ conducted a risk assessment of a food for specified health uses (FOSHU), *Pyuakamu-yosan and Pyuakamu-yosan MV* based on the documents submitted by the applicant and “Stance on Safety Assessments of folic acid (pteroylmonoglutamic acid), reduction of disease risk FOSHU”. *Pyuakamu-yosan and Pyuakamu-yosan MV* are tablet-formed food containing folic acid (pteroylmonoglutamic acid) as the ingredient relevant to its specified health use, “may reduce the risk of birth defects such as spina bifida and other neural tube defects” (labeled with reduction of disease risk claims).

Data used in the assessment include human trials (healthy women) of 12-week continuous consumption and of 4-week continuous 5 fold excessive consumption.

A recommended daily intake of these products, one tablet for *Pyuakamu-yosan*, two tablets for *Pyuakamu-yosan MV* contain 400 µg of pteroylmonoglutamic acid: folic acid as the ingredient relevant to its specified health use. The contained amount is equal to the lower limit of the recommended daily intake of folic acid prescribed in the labeling approval for the Foods for Specified Health Uses²

Based on the above results and the presented documents, FSCJ concluded that *Pyuakamu-yosan* and *Pyuakamu-yosan MV* have no concern relevant to human health as long as pregnant women and women expected to be pregnant observe the recommended daily dose of the products and take them only before and during the first trimester of pregnancy.

¹ “*Pyuakamu-yosan and Pyuakamu-yosan MV*” is a name romanized the product name in Japanese using Hepburn's method for this provisional English translation.

² The policy prescribed in Shoushokuhyou No. 259, Notification of the Deputy Secretary-General of Consumer Affairs Agency, dated 30 October 2014.