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

Risk Assessment Report

Sarashia 100
(Relevant ingredeient: neokotalanol)

(Food for specified health uses)

Food Safety Commission of Japan (FSCJ)

November 2014

ABSTRACT

FSCJ conducted a risk assessment of a food for specified health uses, *Sarashia 100*, based on the documents submitted by the applicant. *Sarashia 100* is a tablet-formed food which contains neokotalanol as the ingredient relevant to its specified health use, “suitable for those who tend to have high postprandial blood glucose levels and also for those who concern in sugar contents in diets”.

A recommended daily intake of *Sarashia 100*, three tablets, contains 663 μg of neokotalanol as an ingredient relevant to its specified use.
The data used in the assessment include experiences of consumption, reverse mutation tests using microorganisms, chromosomal aberration tests using mammalian cells, micronucleus test in mice, a single oral gavage test in rats, 180-day repeated oral gavage tests in rats, a reproductive toxicity study in rats, and tests in humans of single and continuous intakes and consumption of a excess level were conducted in groups of people with normal fasting blood-glucose range, normal high, boundary range and within diabetic ranges.

FSCJ concluded, from the above results, that *Sarashia 100* has no obvious risk relevant to human health as far as the documents submitted by the applicant were concerned.

Since the assessed item is expected to alter blood-glucose level, care must be taken based on the policy prescribed in the Approach to the Safety Assessment of Each Product of Foods for Specified Use[1]. Hence, it is necessary that the applicant make efforts to collect and provide information on the adverse effects. In addition, a note on the consultation to medical personnel for the patients’ intakes needs to be included in a product label.

[1] The policy prescribed in (2) of 2 of the Approach to the Safety Assessment of Each Product of Foods for Specified Health Use (Decision of the Commission dated 10 May 2007).