

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

Risk Assessment Report

Kotara Ekisu

(Relevant ingredient: thiocyclitol derivatives isolated from Kothala-himbutu (neokotalanol))
(Food for specified health uses)

Food Safety Commission of Japan (FSCJ)
October 2014

Abstract

FSCJ conducted a risk assessment of a food for specified health uses, *Kotara Ekisu*, based on the documents submitted by the applicant. *Kotara Ekisu* is a powdered beverage which contains thiocyclitol derivatives isolated from Kothala-himbutu (*Salacia reticulata*) as the ingredient relevant to its specified health use, “suitable for those who tend to have high postprandial blood glucose levels”.

A recommended daily intake of *Kotara Ekisu* contains 0.896 mg of neokotalanol, which is thiocyclitol derivative isolated from Kothala-himbutu.

The data used in the assessment include experiences of consumption, reverse mutation tests using microorganisms, chromosomal aberration tests using mammalian cells, a single oral gavage test in rats, 13-week and 52-week repeated dietary administration tests in rats, a reproductive and developmental toxicity study in rats, and tests in humans of 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 *Kotara Ekisu* 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 Use¹. 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).