

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

Risk Assessment Report

Raresweet

(Food for Specified Health Uses)

Food Safety Commission of Japan (FSCJ)
February 2016

SUMMARY

FSCJ conducted a risk assessment of a food for specified health uses, Raresweet, based on the documents submitted by the applicant. Raresweet is a tabletop sweetener which contains D-psicose as the ingredient relevant to its specified health use, “suitable for those who worry about possible high postprandial blood glucose levels”. The recommended daily intake of this product, 5 g, corresponds to 5 g D-psicose.

The data used in the assessment include human experiences of the consumption, a reverse mutation test using microorganisms, a chromosomal aberration test using mammalian cells, a single oral gavage test, 12-months and 18-months repeated-dietary administration tests and a mid-term hepatocarcinogenicity test in rats, and clinical trials of single and continuous intakes and consumption of an excess level were conducted in groups of volunteers with normal fasting blood-glucose range, normal high, boundary range, with HbA1c of 5.9~6.5%, within diabetic ranges and BMI 25 or more and less than 30.

Based on the results described above and the presented documents, the potential increase in LDL-C following the recommended daily intake of this product was not excluded. An increase in LDL-C does not necessarily link directly to human health. The recommended daily intake of this food is thus considered to have minimal safety risks, if any, for the people who are not suffered from dyslipidemia and also without risks of coronary artery diseases such as diabetes, hypertension and smoking. However, no data are provided to estimate the safety ranges on these risk factors, which allow the people to intake the food without concern. In addition, the information may not be recognized steadily throughout clinical facilities and persons, and thus possible failures of medical care are not excluded for people taking this food. Therefore, patients of high LDL-C viremia or of borderline higher LDL-cholesterolemia should pay attention for the ingestion and should avoid its excessive consumption.

From the above, FSCJ considered it necessary to provide the consumers a complete caution at least for the following points in order to ensure the safety of this food as a food for specified health uses;

- ① Intake of this food has a potential to increase LDL-C, therefore patients from high LDL-C viremia or from borderline higher LDL-cholesterolemia particularly need to be careful on its ingestion.
- ② The excessive consumption of this product should be avoided following the recommended daily intake.

- ③ Consumption of this food in combination with another food containing D-psicose as a raw material should be avoided.

Since the assessed item is expected to alter blood-glucose level, care must be taken based on the policy prescribed in the Stance on 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).