

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

## **Risk Assessment Report**

ヘルシア サツと健膳  
**Herushia Satto Kenzen**  
(Food for Specified Health Uses)

Food Safety Commission of Japan (FSCJ)  
January 2020

### **SUMMARY**

FSCJ conducted a risk assessment of a food for specified health uses, Herushia satto kenzen plain, Herushia satto kenzen plain bottle, Herushia satto kenzen lemon-olive flavored, and Herushia satto kenzen lemon-olive flavored bottle, based on the documents submitted by the applicant. Herushia satto kenzen is a cooking oil which contains alpha-linolenic acid-rich diacylglycerol as the ingredient relevant to its specified health use, “suitable for those who tend to have an extra visceral fat, the higher BMI and also high blood triglycerides level”.

In a 2.5 gram of this product, corresponding to the recommended daily intake, 0.9 gram of alpha-linolenic acid-rich diacylglycerol (as alpha-linoleic acid) is contained.

The data used in the assessment include experiences of consumption, genotoxicity study, developmental toxicity study in rats, 90-day repeated dietary administration test in rats. In addition, the data include a human study of 12-week continuous consumption in persons with BMI of 25 or above but less than 30 and visceral fat of 125 cm<sup>2</sup> or more, a study of 4-week continuous 3 fold excessive consumption in persons with BMI of 18.5 or above but less than 30, and a study of 4-week continuous 5 fold excessive consumption in persons with BMI of 22 or above but less than 30.

There is no toxic effects in animal studies arousing food safety concerns, and no abnormalities in clinical laboratory test value and no clinical adverse events in human trials, although the history of safe use of estimated daily intake of this product as food is not enough. Consequently, FSCJ concluded that “Herushia satto kenzen plain, Herushia satto kenzen plain bottle, Herushia satto kenzen lemon-olive flavored, and Herushia satto kenzen lemon-olive flavored bottle” has no obvious risk to human health as far as the documents submitted by the applicant were concerned.

However, a glycidol fatty acid ester content in the assessed item need to be continuously kept as low as possible according to the principle of ALARA (As Low As Reasonably Achievable).