



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

Risk Assessment Report

Sukoyaka Sesame Oil (Food for Specified Health Uses)

Food Safety Commission of Japan (FSCJ)
April 2019

SUMMARY

FSCJ conducted a risk assessment of Sukoyaka Sesame Oil, an edible cooking oil as a Specified Health Product aiming for the care of blood LDL cholesterol levels. This product contains sesamin and sesamolins as relevant ingredients. The assessment was conducted based on the documents submitted by the applicant.

The recommended daily intake, 14 g, of this product contains 77.8 mg of sesamin and 28.7 mg of sesamolins.

The assessed data include history of use as the food, *in-vitro* studies, *in-vivo* animal studies on genotoxicity and repeated dose toxicity, human trials, and others. The human trials include single consumption in healthy individuals of BMI 18<25, 12-week continuous consumption in a group of people whose LDL cholesterol levels were 120~160 mg/dL, and 4-week continuous 3-fold excessive consumption in groups of people whose LDL cholesterol levels were less than 120 mg/dL and 120-160 mg/dL.

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 “Sukoyaka Sesame Oil” has no obvious risk to human health as far as the documents submitted by the applicant were concerned.

Since potential drug interaction of this product with anticoagulant drugs such as Warfarin cannot be excluded, caution for such drug interactions needs to be displayed as the information for the recipients and medical personnel, specifically for drugs that may have such a potential but not for every medicinal products. In addition, caution for preventing excess consumption of this product must be displayed clearly as possible, since 12-week continuous consumption study showed that the daily energy intake increased at the end of 12 weeks compared to the level before the start of the study.