

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

Risk Assessment Report

松谷のミニビスケット

*Matsutani no mini bisuketto*¹

(A small buiscuit containing highly cross-linked starch
(distarch phosphate made from tapioca starch))
(Food for specified health uses)

Food Safety Commission of Japan (FSCJ)

March 2017

ABSTRACT

FSCJ conducted a risk assessment of a food for specified health uses (FOSHU), *Matsutani no mini bisuketto*, based on the documents submitted by the applicant. *Matsutani no mini bisuketto* is a bisuciuat containing highly cross-linked starch (distarch phosphate made from tapioca starch) as the ingredient relevant to its specified health use, “suitable for those who would like to keep the stomach in good condition and for those who are concerned about digestive function”

The recommended daily intake of this product, 28 g, contains 7 g of highly cross-linked starch (distarch phosphate made from tapioca starch) (dietary fiber).

The assessed data include reverse mutation tests using microorganisms, a single oral gavage test in rats, 28-day repeated oral gavage tests in rats, and human trials of 12-week continuous consumption and of 4-week continuous 3 fold excessive consumption in healthy individual and individual who have constipation tendency.

Based on the above results and the presented documents, FSCJ concluded that *Matsuya no mini bisuketto* has no concern relevant to human health as long as the presented documents concern.

However, since the safety has not been established in children and infants, cautions for children (’s intake) need to be included in the product label. Considering that this product is a confectionery (biscuit formed food), a clear note on avoidance of excessive intake should be necessary.

¹ “*Matsutani no mini bisuketto*” is a name romanized the product name in Japanese using Hepburn's method for this provisional English translation.