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Risk Assessment Report

Kishiritoru Oratekutogamu

(Relevant ingredient: eucalyptus extract (as macrocarpal C))

(Food for specified health uses)

Food Safety Commission of Japan (FSCJ)
November 2014

ABSTRACT

FSCJ conducted a risk assessment of a food for specified health uses, *Kishiritoru Oratekutogamu* <Kuriaminto> and *Kishiritoru Oratekutogamu* <Supeaminto>, based on the documents submitted by the applicant. *Kishiritoru Oratekutogamu* <Kuriaminto> and <Supeaminto> are chewing gums which contains eucalyptus extract as the ingredient relevant to its specified health use, “to reduce dental plaque and keep one's gingival health”.

A recommended daily intake of *Kishiritoru Oratekutogamu*, 10 grains, contains 0.48 mg of eucalyptus extract (as macrocarpal C) as the ingredient relevant to its specified use.

The data used in the assessment include the reverse mutation tests in microorganisms, chromosomal aberration tests using mammalian cells, the micronucleus tests in rats, a single gavage administration test, 90-day repeated gavage administration test. Data were also used from human studies of continuous intake in persons who suffered from gingival inflammation, and of continuous overdose in healthy persons and gingivitis patients.

FSCJ concluded, from the above results, that *Kishiritoru Oratekutogamu* <Kuriaminto> and *Kishiritoru Oratekutogamu* <Supeaminto> have no obvious risk relevant to human health as far as the documents submitted by the applicant were concerned.