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

Risk Assessment Report

Itaconic acid
(Exempted Substances[1])

Food Safety Commission of Japan (FSCJ)
April 2015

ABSTRACT

FSCJ conducted a risk assessment necessary for designating itaconic acid (CAS No. 97-65-4), a plant growth regulator, as an Exempted Substance[1] using results from various studies.

Itaconic acid has been approved as an existing food additive, and was recognized as a substance which did not need immediate evaluation of safety at the moment, in "Investigation on safety assessments of existing food additives" conducted by the Ministry of Health, Labour and Welfare in 1999. Itaconic acid has been designated as a deleterious substance since September 2012, and strong stimulus to the eye mucosa by this substance was obsereved by an eye irritation test. In an acute toxicity study with oral dose of 2,560 mg/kg bw or more, ataxia, piloerection and decreased weight gain were observed. However, no other effect relevant to human health attributable to itaconic acid was observed in other toxicity studies.

In addition, when itaconic acid is used as a pesticide instead of as a food additive, excessive ingestion of residues in crops through food resulted from such a usage is very unlikely to occur.
Consequently, FSCJ concluded that risks of itaconic acid to human health through residues in foods are negligible as long as normally used as a pesticide.

[1] On May 29, 2006 the Ministry of Health, Labour and Welfare (MHLW) introduced the positive list system for agricultural chemicals remaining in foods to prohibit the distribution of foods that contain agricultural chemicals above a certain level if maximum residue limits (MRLs) have not been established. Exempted Substances are designated as substances having no potential to cause damage to human health by the Minister of Health, Labour and Welfare, based on the provision of Paragraph 3, Article 11 of the Food Sanitation Law, and these substances are not subjected to the positive list system.