

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

Risk Assessment Report

Chitin-glucan

(Food Additive)

Food Safety Commission of Japan (FSCJ)
November 2020

ABSTRACT

The FSCJ conducted a risk assessment of “Chitin-glucan”, an additive used as a filter aid, based on results from various studies.

The data of the following studies were analyzed: pathogenicity and toxicogenicity of *Aspergillus niger*; and toxicokinetics, genotoxicity, acute toxicity, repeated dose toxicity and epidemiology of chitin-glucan.

The FSCJ determined that the *Aspergillus niger* properly managed to produce “Chitin-glucan” has no pathogenicity when it is consumed as a food additive.

Further, the FSCJ observed that fumonisin and ochratoxin A derived from the additive “Chitin-glucan” would not give adverse effects on human health because the projected maximum exposure of neither aggregate fumonisin nor ochratoxin A exceeds respective TDI (Tolerable Daily Intake) even though each is overestimated.

Meanwhile, the FSCJ thought that risk management organizations should seriously examine measures such as a periodical monitoring of mycotoxin contamination and others as it cannot be denied that fungus other than above projected ones might be applied.

The FSCJ decided to examine the safety of “Chitin-glucan” since there was no particular safety concern about the components of this product: chitin and β -glucan. The FSCJ found that chitin-glucan is hardly absorbed in the gastrointestinal tract due to its insolubility.

The FSCJ did not observe genotoxicity in chitin-glucan under the condition of the limited results of its study.

The FSCJ identified the NOAEL of 6.6 g/kg bw per day in male and 7.0 g/kg bw per day in female of the 10% dosed group, the highest dose administered orally in a 13-week rat study (Jonker et al. 2010).

The FSCJ did not observe adverse effects at the dose of 4.5 g/day chitin glucan administered in a 6-week human intervention study (Bays et al. 2013).

The FSCJ estimated the daily intake of chitin-glucan from wine to be 4.37 mg/kg bw per day assuming that chitin-glucan would be used in the maximum dose stipulated in the final draft of “Standards for Use” and that all of the additive amounts may remain in the wine. The intake of 4.37 mg/kg per day is presumed to be an overestimate.

The FSCJ concluded that the additive “Chitin-glucan” had no safety concern as long as used appropriately as food additive, examining the following points as well as presently available findings:

- 1) The draft “Standards for Use” stipulates that the additive “Chitin-glucan” is removed before producing the final product;
- 2) Chitin-glucan is insoluble and hardly absorbed through gastrointestinal tract; and
- 3) No toxicity was observed for the daily intake of 4.5 g/day “chitin-glucan” in human intervention study.