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

Risk Assessment Report

Polyvinyl alcohol

(Food Additives)

Food Safety Commission of Japan (FSCJ)

June 2023

ABSTRACT

The FSCJ conducted a risk assessment of "polyvinyl alcohol," an additive used as a food manufacturing agent, based on results from submitted documents.

Methyl acetate and methanol are known to be impurities generating during the manufacturing process of polyvinyl alcohol, hereinafter mostly abbreviated as "PVA." Methyl acetate is decomposed into methanol and acetic acid. Accordingly, a comprehensive risk assessment of PVA was conducted by incorporating the existing findings on methanol and acetic acid into the findings on PVA itself.

The data used in the assessment include information about toxicokinetics, genotoxicity, acute toxicity, repeated dose toxicity and reproductive/developmental toxicity of PVA as test substance, and the existing findings in humans.

1. PVA

PVA with a molecular weight of 5,000 to 50,000 was very poorly absorbed when orally administered, and therefore, its principal route of excretion was considered to be in the feces. On the other hand, intravenously administered PVA with low molecular weights was rapidly excreted in the urine, and the excretion was delayed as the molecular weight increased.

The FSCJ judged that PVA was not genotoxic.

The no-observed-adverse-effect level (NOAEL) of PVA was assumed to be 5,000 mg/kg bw per day, based on the highest dose in both of a 90-day rat repeated dose toxicity study and a rat reproductive toxicity study.

The estimated daily intakes of PVA were calculated to be 590 mg/person per day (11 mg/kg bw per day) for national average, and 370 mg/person per day (23 mg/kg bw per day) for children.

Since PVA is virtually not absorbed in the gastrointestinal tract, and no evidence of toxicity was observed up to the highest dose of 5,000 mg/kg bw per day in both of the 90-day rat repeated dose toxicity study and the rat reproductive toxicity study, respectively, FSCJ judged that PVA poses no safety concern relevant to human health as long as used appropriately as an additive, and thus that it was deemed unnecessary to specify an ADI.

2. Methanol

Risk of methanol was assessed by the FSCJ in 2019. Since then, no additional toxicokinetic and toxicological evaluations have been made owing to lack of new findings. The estimated daily intakes (EDI) of methanol derived from PVA were calculated to be 0.15 mg/kg bw per day for national average and 0.32 mg/kg bw per day for children. From existing findings in humans, methanol intakes from a regular diet were calculated to be 2.0 mg/kg bw per day for national average and 0.81 mg/kg bw per day for children. On the other hand, FDA established the acceptable daily intake (ADI) of methanol to be 7.1 - 8.4 mg/kg bw per day. Since it was considered that methanol from PVA is absorbed, metabolized *in vivo* and excreted as the same way as methanol derived from regular diets, the FSCJ judged that methanol derived from PVA poses no safety concern relevant to human health as long as PVA are used appropriately as an additive.

3. Acetic acid

Risk of acetic acid was assessed by the FSCJ in 2017. Since then, no additional toxicokinetic and toxicological evaluations were made owing to lack of new findings. The estimated intake of acetic acid derived from PVA was low (5.0 mg/person per day for national average and 3.6 mg/person per day for children), compared with that from the regular dietary intake (130 - 520 mg/person per day). The FSCJ, therefore, judged that acetic acid derived from PVA poses no safety concern as long as PVA are used appropriately as an additive.

Given all of the above assessment results, the FSCJ concluded that PVA poses no safety concern relevant to human health as long as used appropriately as an additive, and thus it was deemed unnecessary to specify an ADI.