

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

Risk Assessment Report

Hydroxypropyl Distarch Phosphate

(Exempted Substances)

Food Safety Commission of Japan (FSCJ)

October 2017

ABSTRACT

FSCJ conducted a risk assessment of hydroxypropyl distarch phosphate (CAS No. 53124-00-8), an insecticide (an acaricide) where validity to designate it as an Exempted Substance¹ was evaluated based on various documents including FSCJ assessment reports on the relevant substance as a food additives.

Processed starches including hydroxypropyl distarch phosphate have been assessed by FSCJ as food additives, and FSCJ considered it appropriate to use the data of the assessment conducted as a food additives for the present assessment of this item as an exempted substance.

Increased organ weights of the caecum and calcium deposits in the kidney were observed at high doses of hydroxypropyl distarch phosphate in toxicity studies. FSCJ considered that either effects is of little relevance to human health in line with the previous assessment of the item as a food additive.

In addition, FSCJ recognized that excessive ingestion of this item is very unlikely to occur comparing to the ingestion as the food additives, if hydroxypropyl distarch phosphate is ingested as a pesticide residue in food.

Consequently, FSCJ concluded that risks of hydroxypropyl distarch phosphate on human health through the pesticide residue in foods are negligible under appropriate usage of this compound as a pesticide taking into account the conclusion of assessment as the food additive.

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.