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

Risk Assessment Report

Methyl pyruvate and ectozoon parasiticide containing methyl pyruvate as an active ingredient utilized for Tetraodontiformes [Marinedip]

(Veterinary medicinal products)

Food Safety Commission of Japan (FSCJ)

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ABSTRACT

FSCJ conducted a risk assessment for methyl pyruvate (CAS No. 600-22-6) and ectozoon parasiticide (Marinedip) containing methyl pyruvate as an active ingredient utilized for Tetraodontiformes based on a written application for marketing approval of a new veterinary medicinal product, etc.

Methyl pyruvate, the active ingredient of this veterinary medicinal product, is categorized into designated additives among food additives and is approved for use in fragrances in Japan. The results from pharmacokinetic studies and residue tests suggest that methyl pyruvate, the active ingredient of this veterinary medicinal product, is decomposed into pyruvic acid over time during bath treatment in sea water. The concentration of methyl pyruvate in each tissue of skin, muscles and others was below the detection limit even right after the bath treatment. Therefore, it was considered that only a small amount of methyl pyruvate was absorbed in Japanese pufferfish (Takifugu rubripes) and promptly metabolized and decomposed in vivo. From the above data, FSCJ determined that it was not necessary to specify an ADI for methyl pyruvate.

Methyl lactate, a metabolite of methyl pyruvate, is approved as a food additive for the same use as methyl pyruvate in Japan. Also, methyl lactate is found in food such as raw sardine. It was suggested that methyl lactate, which was detected in pharmacokinetic studies and residue tests, is likely to be from a feed or an endogenous compound produced in the body of Japanese pufferfish. A Japanese pufferfish was dipped in double-dosed methyl pyruvate at 600 ppm for 15 minutes. The concentration of methyl lactate measured after one day from the completion of the treatment was similar to that of wild Japanese pufferfish. Based on these findings, FSCJ determined that it is also not necessary to specify an ADI for methyl lactate.

This veterinary medicinal product does not contain any excipient, etc.

Consequently, FSCJ concluded that the risk to human health through consumption of aquatic foods from the parameters assessed is negligible as long as it is appropriately used.