FOOD SAFETY

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Methyl Pyruvate and Marinedip

Summary

Food Safety Commission of Japan

The Food Safety Commission of Japan (FSCJ) conducted a risk assessment for methyl pyruvate (CAS No. 600–22-6) and Marinedip, an ectozoon parasiticide containing methyl pyruvate as an active ingredient for *Tetraodontiformes*, based on documents including a written application for marketing approval of a new veterinary medicinal product. Methyl pyruvate, a designated additive, is approved for use in fragrances in Japan. In pharmacokinetic studies, methyl pyruvate is gradually decomposed into pyruvic acid in sea water during bath treatment of fish. The concentration of methyl pyruvate in each tissue of skin, muscles and others was already below the detection limit soon after the bath treatment. Therefore, an amount of methyl pyruvate absorbed, if any, was minimal and/or rapidly metabolized in Japanese pufferfish (*Takifugu rubripes*). It is thus unnecessary to specify an acceptable daily intake (ADI) for methyl pyruvate. Methyl lactate, a metabolite of methyl pyruvate, is also approved as a food additive in Japan and methyl lactate is found in food such as raw sardine. It was suggested that methyl lactate is derived from a feed or an endogenous compound produced in the body of Japanese pufferfish. A Japanese pufferfish was dipped in excess amount (2 × 300 ppm) of methyl pyruvate for 15 minutes. Muscle levels of methyl lactate of non-treated wild Japanese pufferfish did not differ from those of fish treated with methyl pyruvate measured at one to five days after the treatment. Based on these findings, it was unnecessary to specify an ADI for methyl lactate. Consequently, FSCJ concludes that the risk to human health through consumption of aquatic foods from the parameters assessed is negligible as long as Marinedip is appropriately used.

Conclusion in Brief

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

Methyl pyruvate, the active ingredient of this veterinary medicinal product, is a designated additive approved for use in fragrances in Japan. In pharmacokinetic studies, methyl pyruvate, the active ingredient of this veterinary medicinal product, is gradually decomposed into pyruvic acid in sea water during bath treatment of fish. The concentration of methyl pyruvate in each tissue of skin, muscles and others was already below the detection limit soon after the bath treatment. Therefore, an amount of methyl pyruvate absorbed, if any, was minimal and/or rapidly metabolized in Japanese pufferfish (*Takifugu rubripes*). It is thus unnecessary to specify an acceptable daily intake (ADI) for methyl pyruvate.

Methyl lactate, a metabolite of methyl pyruvate, is also approved as a food additive in Japan and 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 derived from a feed or an endogenous compound produced in the body of Japanese pufferfish. A Jap-

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anese pufferfish was dipped in excess amount (2 × 300 ppm) of methyl pyruvate for 15 minutes. Muscle levels of methyl lactate of non-treated wild Japanese pufferfish did not differ from those of fish treated with methyl pyruvate measured at one to five days after the treatment. Based on these findings, it was unnecessary to specify an ADI for methyl lactate.

This veterinary medicinal product does not contain any excipients.

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