

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

Risk Assessment Report

Econor 1% premix (Veterinary Medicinal Products)

Food Safety Commission of Japan (FSCJ)
November 2018

ABSTRACT

FSCJ conducted a risk assessment of Econor 1% premix, a feed additive for pigs which contains valnemulin hydrochloride as an active ingredient, based on a written application for reevaluation of veterinary medicinal products.

Import and sale of this product as a veterinary medicinal product has been approved for use in pigs against swine dysentery, mycoplasmal pneumonia of swine and porcine proliferative enteritis, and the ADI for its active ingredient has been specified by FSCJ as 0.008 mg (as valnemulin)/kg bw/day.

Regarding the additives used in this formulation, FSCJ concludes that considering the usage, existing toxicity data, and the dosage and administration, the risk to human health from the intake of these additives as ingredient of this product is negligible.

In addition, as long as concerning the data from the applicants, no finding to suggest any concern of this product for food safety were reported during the reevaluation period. New findings to suggest concern for toxicity relevant to human health through food consumption was not obtained in a literature search after the reevaluation period.

Hence, FSCJ concluded that the risk to human health from the intake of this product through consumption of foods is negligible as long as it is appropriately used.

Besides, in use of this product, special attention needs to be paid for the risk evaluation of antimicrobial-resistant bacteria which is to be conducted, since valnemulin hydrochloride is a pleuromutilin (Pleuromulin) antibiotic agent.

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Regarding the additives used in this formulation, FSCJ concludes that considering the usage, existing toxicity data, and the dosage and administration, the risk to human health from the use of this additive as ingredient of this product into the target animals is negligible.

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