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

Risk Assessment Report

Vecoxan containing diclazuril as an active ingredient

(Veterinary Medicinal Products)

Food Safety Commission of Japan (FSCJ)
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ABSTRACT

FSCJ conducted a risk assessment of vecoxan submitted for a new veterinary medicinal product by an applicant. Vecoxan, an oral drench for veterinary use in cattle, contains diclazuril as an active ingredient.

Diclazuril, the main ingredient of vecoxan, has been already approved as a veterinary medicinal product and feed additive by several national authorities except Japan. In Japan, FSCJ has specified the acceptable daily intake (ADI) for diclazuril as 0.03 mg/kg bw/day.

Regarding the additives used as ingredients in this product, FSCJ considered that their risk as ingredient of this product for human health was negligible when considering the usage, existing toxicity data, and the dosage and administration,.

In feeding studies with single oral administration of clinical dose of this product in calves, the maximum amount of residues of diclazuril was detected in the liver one day after the administration at 0.041 μg/g, and reduced to a level below the detection limit in the liver, kidney, adipose tissue and small intestine ranging from 0.004 μg/g to 0.014μg/g, three days after the administration. In all cases residue level of diclazuril was below the detection limit in the muscle.
The safety studies and clinical studies of this product indicated that this product has no concern for cows.

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