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

Risk Assessment Report

Diclazuril

(Veterinary Medicinal Products)

Food Safety Commission of Japan (FSCJ)

May 2014

ABSTRACT

FSCJ conducted a risk assessment of a parasiticide, diclazuril (CAS No. 101831-37-2), using results from various studies and others.

The data used in the assessment are on: pharmacokinetics (mice, rats, rabbits, cattle, sheep, horses, pigs, chicken and turkeys), residues (cattle, sheep, pigs, rabbits, chicken, turkeys and pheasants), genotoxicity and acute toxicity (mice, rats, rabbits and dogs), subacute toxicity (rats, mice, rabbits and dogs), chronic toxicity and carcinogenicity (mice, rats and dogs), reproductive toxicity (rats and rabbits), pharmacological effects and others.

All genotoxicity studies on diclazuril gave negative results. No carcinogenicity was observed in combined chronic toxicity/carcinogenicity studies in mice and rats. Therefore, FSCJ concluded that diclazuril is not a genotoxic carcinogen and its acceptable daily intake (ADI) can be specified.

The effect identified at the lowest dose in the toxicity studies of diclazuril was lesions of the liver observed in a 25-month combined chronic toxicity/carcinogenicity study in mice, and NOAEL was 3 mg/kg bw/day.

Applying the safety factor of 100 (10 for species difference and 10 for individual difference) to the NOAEL, FSCJ specified the ADI for diclazuril to be 0.03 mg/kg bw/day.