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

Risk Assessment Report

Closantel

(Veterinary Medicinal Products)

Food Safety Commission of Japan (FSCJ)
April 2015

ABSTRACT

FSCJ conducted a risk assessment of closantel (CAS No. 57808-65-8), an antiparacitic agent, based on documents including reports of the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

Data used in the assessment include pharmacokinetics (rats, cattle and sheep), metabolism (rats, cattle and sheep), residues (cattle and sheep), genotoxicity, acute toxicity (mice, rats, cattle and sheep), subacute toxicity (rats and dogs), carcinogenicity (mice and rats) and reproductive developmental toxicity (rats and rabbits).

No genotoxicity relevant to human health was observed from various genotoxicity studies. It was considered that closantel was not a genotoxic carcinogen since carcinogenicity was not detected in carcinogenicity studies in mice and rats. Hence, FSCJ concluded that an acceptable daily intake (ADI) could be specified.

The toxic effects identified at the lowest dose in the toxicological studies of cloantel include a slight increase in blood glucose levels and increased incidence of spermatic granulomas in the epididymides in a 13-week subacute toxicity study in rats; increased incidence of spermatic granulomas in the epididymides in a 24-month carcinogenicity study in rats; and an increase in total bilirubin in a 3-month subacute toxicity study in dogs. The no-observed-adverse-effect level (NOAEL) obtained in all of the above toxicological studies was 2.5 mg/kg bw/day.

Applying a safety factor of 100 (10 for species difference and 10 for individual difference) to the NOAEL, FSCJ specified an ADI of 0.025 mg/kg bw/day.