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

Risk Assessment Report

Morantel (Veterinary medicinal products/Feed additives)

Food Safety Commission of Japan (FSCJ)

August 2013

ABSTRACT

FSCJ conducted a risk assessment of “morantel (CAS No. 20574-50-9)”, a tetrahydro-pyrimidine anthelmintic, based on evaluation reports from the EMEA, documents from the FDA and others.

The data used in the assessment are on; pharmacokinetics (mice, rats, dogs, cows, pigs and sheeps), residues (cows, pigs and sheeps), genotoxicity, acute toxicity (mice, rats and dogs), subacute toxicity (rats and dogs), chronic toxicity and carcinogenicity (dogs and rats), as well as reproductive and developmental toxicity (mice, rats and rabbits).

All genotoxicity studies on morantel gave negative results. The combined chronic toxicity/carcinogenicity study showed no significant dose-dependent trend in tumor incidence, and no structural alert in carcinogenicity is recognized in the chemical structure of morantel. These findings suggest that morantel is not a genotoxic carcinogen. Therefore, FSCJ concluded that an acceptable daily intake (ADI) for morantel can be specified.

The effects observed at the lowest dose in the toxicity studies of morantel included frequent vomiting in dogs in a 2-year chronic toxicity study and suppression of body weight gain in female rats in a 2-year combined chronic toxicity/carcinogenicity study. The no observed adverse effect level (NOAEL) in these studies was 1.2 mg/kg bw/day.

FSCJ specified an ADI of 0.012 mg/kg bw/day for morantel based on the NOAEL, applying a safety factor of 100 (10 for interspecies difference and 10 for inter-individual difference).