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

Risk Assessment Report

Fosetyl

(Pesticides)

Food Safety Commission of Japan (FSCJ)
January 2016

ABSTRACT

FSCJ conducted a risk assessment of fosetyl (CAS No. 39148-24-8), fungicides, based on results from various studies.

The data used in the assessment include fate in animals (rats), fate in plants (tomatoes and apples), residues in crops, subacute toxicity (rats and dogs), chronic toxicity (rats and dogs), carcinogenicity (rats and mice), three-generation reproductive toxicity (rats), developmental toxicity (rats and rabbits), and genotoxicity.

Major adverse effects of fosetyl observed are inflammation and transitional cell hyperplasia in the urinary bladder (male rats only) and tubular degeneration in the testis (dogs only). Fosetyl showed no reproductive toxicity, teratogenicity and genotoxicity relevant to human health.

Incidence of transitional cell tumors in the urinary bladder was increased in a two-year carcinogenicity study in male rats. No genotoxic mechanism was involved in the increase. It could be thus established a threshold value for the increase.

Fosetyl and phosphorous acid, a metabolite/degradate in animals, plants or soil, were identified as relevant substances for the residue definition for dietary risk assessment in agricultural products.

The lowest no-observed-adverse-effect level (NOAEL) obtained in all toxicity studies was 88 mg/kg bw/day in a two-year carcinogenicity study in rats. FSCJ specified an acceptable daily intake (ADI) of 0.88 mg/kg bw/day by applying a safety factor of 100 to the NOAEL.

The lowest NOAEL or lowest-observed-adverse-effect level (LOAEL) for potential adverse effects of a single oral administration of fosetyl was 1,000 mg/kg bw in a developmental toxicity study in rats. FSCJ concluded it unnecessary to specify an acute reference dose (ARfD), because the NOAEL was above the cut-off level (500 mg/kg bw).