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

Risk Assessment Report

Bromacil

(Pesticides)

Food Safety Commission of Japan (FSCJ)
May 2016

ABSTRACT

FSCJ conducted a risk assessment of bromacil (CAS No.314-40-9), a uracil herbicide, based on results from various studies.

The data used in the assessment include the fate in animals (rats), fate in plants (oranges and pineapples), residues in crops, chronic toxicity (dogs), combined chronic toxicity/carcinogenicity (rats), carcinogenicity (mice), two-generation reproductive toxicity (rats), developmental toxicity (rats and rabbits), and genotoxicity.

Major adverse effects of bromacil were reduction of body weight gain, increased liver weights, hepatocellular hypertrophy, and testicular atrophy with necrosis of spermatocytes (mice only). Bromacil had no reproductive toxicity, teratogenicity and genotoxicity relevant to human health.

Total incidences of hepatocellular adenomas and carcinomas showed an increased tendency in a carcinogenicity study in mice. However, nogenotoxic mechanism was involved in the increase. Therefore it could be established a threshold dose for the increase.

Bromacil (parent compound only) was identified as the relevant substance for the residue definition for dietary risk assessment in agricultural products.

The lowest no-observed-adverse-effect level (NOAEL) in all toxicity studies was 1.96 mg/kg bw/day in a two-year combined chronic toxicity/carcinogenicity study in rats. FSCJ specified an acceptable daily intake (ADI) of 0.019 mg/kg bw/day by applying a safety factor of 100 to the NOAEL.

The lowest NOAEL for potential adverse effects of a single oral administration of bromacil was 20 mg/kg bw/day obtained in developmental toxicity studies in rats. FSCJ specified an acute reference dose (ARfD) to be 0.2 mg/kg bw by applying a safety factor of 100 to the NOAEL.