

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

Risk Assessment Report

Prometryn (Pesticides)

Food Safety Commission of Japan (FSCJ)
September 2015

ABSTRACT

FSCJ conducted a risk assessment of prometryn (CAS No.7287-19-6), a methylthio-s-triazine herbicide based on results from various studies.

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

Major adverse effects of prometryn were reduced gain of body weight, anemia, and increase liver and kidney weights. No neurotoxicity, carcinogenicity, reproductive toxicity, teratogenicity or genotoxicity were observed.

Based on the above results, prometryn (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) was 3 mg/kg bw/day in a two-year chronic toxicity study in dogs. FSCJ specified an acceptable daily intake (ADI) of 0.03 mg/kg bw/day, applying a safety factor of 100 to the NOAEL.

The lowest NOAEL for potential adverse effects of a single oral administration of prometryn was 150 mg/kg bw based on clinical signs in an acute neurotoxicity study in rats. Consequently, FSCJ specified an acute reference dose (ARfD) of 1.5 mg/kg bw, applying a safety factor of 100 to the NOAEL.