

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

Risk Assessment Report

Fluoroimide (Pesticides)

Food Safety Commission of Japan (FSCJ)

October 2013

ABSTRACT

FSCJ conducted a risk assessment of a maleimide-structure fungicide “fluoroimide” (CAS No. 41205-21-4) based on the summary reports made by applicants and others.

The data used in the assessment are on; toxicokinetics in animals (rats), fate in plants (crab apple and apple leaf cultured cell), subacute toxicity (rats and mice), subacute neurotoxicity (rats), chronic toxicity (dogs), combined chronic toxicity/carcinogenicity (rats), carcinogenicity (mice), reproductive toxicity (rats), developmental toxicity (rats and rabbits), and genotoxicity.

Major adverse effects of fluoroimide observed are: decreased body weight gain, decreased feed consumption, effects on blood such as anemia and others, and forestomach mucosal edema.

No carcinogenicity, neurotoxicity, developmental toxicity or genotoxicity was observed.

Based on the results from various studies, FSCJ specified the residue definition for this dietary risk assessment in agricultural products to be fluoroimide (parent compound only).

A three-generation reproductive toxicity study in rats demonstrated that fluoroimide affects reproductive ability at a high dose which exerts general toxicity in parent animals, and the no-observed adverse effect level (NOAEL) could not be specified. On the other hand, effects on reproductive ability were not observed in a two-generation reproductive toxicity study in rats, and NOAEL was specified in two-year combined chronic toxicity/carcinogenicity studies in rats conducted at a lower dose for a longer period of time. Based on these results, FSCJ concluded that the NOAEL covered the general toxicity, effects on reproductive ability and effects on next generations observed in the three-generation reproductive toxicity study in rats.

The minimum value of NOAEL or lowest observed adverse effect level (LOAEL) in the toxicological studies was NOAEL of 9.28 mg/kg body weight per day in a two-year combined chronic toxicity/carcinogenicity study in rats. Dividing the NOAEL by the safety factor of 100, FSCJ specified the acceptable daily intake (ADI) to be 0.092 mg/kg body weight per day.