

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

Risk Assessment Report

Oxathiapiprolin

(Pesticides)

Food Safety Commission of Japan (FSCJ)

July 2015

ABSTRACT

FSCJ conducted a risk assessment of oxathiapiprolin (CAS No. 1003318-67-9), a piperidinyl thiazole isoxazoline class of fungicide, based on results from various studies.

The studies include the fate in animals (rats), fate in plants (potatoes and lettuce), residues in crops, subacute toxicity (rats, mice and dogs), chronic toxicity (dogs), combined chronic toxicity/carcinogenicity (rats), carcinogenicity (mice), two-generation reproductive toxicity (rats), developmental toxicity (rats and rabbits), genotoxicity and immunotoxicity.

Major adverse effects of oxathiapiprolin observed are decreased body weight gain and delayed preputial separation in rat offspring in a two-generation reproductive toxicity study.

No neurotoxicity, carcinogenicity, reproductive toxicity, teratogenicity or genotoxicity were observed.

Based on the above results, oxathiapiprolin (parent compound only) was identified as the residue definition for dietary risk assessment in agricultural products.

The lowest no-observed-adverse-effect level (NOAEL) obtained in all studies was 346 mg/kg bw/day in a two-generation reproductive toxicity study in rats. Applying a safety factor of 100 to the NOAEL, FSCJ specified an acceptable daily intake (ADI) of 3.4 mg/kg bw/day.

FSCJ considered it unnecessary to specify an acute reference dose (ARfD), since it is unlikely that oxathiapiprolin exerts adverse effects due to a single dose administration.