

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

Risk Assessment Report

Fenazaquin

(Pesticides)

Food Safety Commission of Japan (FSCJ) September 2016

ABSTRACT

FSCJ conducted a risk assessment of fenazaquin (CAS No. 1290928-09-8), a quinazoline fungicide, based on results from various studies.

The data used in the assessment include the fate in animals (rats), comparison of toxicokinetics (rats, mice and hamsters), fate in plants (grapes and apples), residues in crops, subacute toxicity (rats, hamsters and dogs), chronic toxicity (dogs), combined chronic toxicity/carcinogenicity (rats), carcinogenicity (hamsters), two-generation reproductive toxicity (rats), developmental toxicity (rats and rabbits), immunotoxicity (rats) and genotoxicity.

Major adverse effects of fenazaquin were depression of body weight. None of carcinogenicity, reproductive toxicity, teratogenicity, immunotoxicity and genotoxicity relevant to human health were observed.

Based on the results of various studies, fenazaquin and its metabolite M12 were identified as substances for the residue definition in agricultural products.

The lowest no-observed-adverse-effect level (NOAEL) obtained in all the studies was 0.46 mg/kg bw/day in a two-year combined chronic toxicity/carcinogenicity study. Applying a safety factor of 100 to the NOAEL, FSCJ has established an acceptable daily intake (ADI) of 0.0046 mg/kg bw/day.

The lowest NOAEL for adverse effects that would be likely to be elicited by a single oral administration of fenazaquin was 10 mg/kg bw/day, which is obtained on the developmental toxicity study in rats. FSCJ specified an acute reference dose (ARfD) of 0.1 mg/kg bw/day, applying a safety factor of 100 to the NOAEL.