

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

Risk Assessment Report

Mepiquat-Chloride (Pesticides)

Food Safety Commission of Japan (FSCJ) March 2017

ABSTRACT

FSCJ conducted a risk assessment of Mepiquat-Chloride (CAS No. 24307-26-4), a heterogeneous plant growth regulator, based on results from various studies.

The data used in the assessment include fate in animals (rats, goats and chiken), fate in plants (cotton and grape), residues in crops, subacute toxicity (rats, mice and dogs), subacute neurotoxicity (rats), chronic toxicity (rats and dogs), combind chronic toxicity/carcinogenicity (mice), carcinogenicity (rats and mice), two- and three-generation reproductive toxicity (rats), developmental toxicity (rats and rabbits), developmental neurotoxicity (rats) and genotoxicity.

Major adverse effects of mepiquat-chloride observed are depressed body weight, epithelial vacuolation in the distal convoluted tubules in dogs and clinical signs such as tremor. Fluthiacet-methyl showed no carcinogenicity, adverse effects on reproduction, teratogenicity, developmental neurotoxicity and genotoxicity.

Based on the results from various studies, only mepiquat-chloride (parent compound only) was identified as the residue definition for dietary risk assessment in agricultural products.

The lowest no-observed-adverse-effect level (NOAEL) in adequate number of toxicological studies was 30 mg/kg bw/day of maternal toxicity in developmental neurotoxicity in rats. FSCJ specified an acceptable daily intake (ADI) of 0.3 mg/kg bw/day by applying a safety factor of 100 to the NOAEL.

The lowest NOAEL for potential adverse effects of single oral administration of mepiquat-chloride was 30 mg/kg bw/day obtained in developmental neurotoxicity in rats. FSCJ specified an acute reference dose (ARfD) to be 0.3 mg/kg bw applying a safety factor of 100 to the NOAEL.