

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

Risk Assessment Report

Dichlobenil

(Pesticides)

Food Safety Commission of Japan (FSCJ)

July 2014

ABSTRACT

FSCJ conducted a risk assessment of dichlobenil (CAS No. 1194-65-6), an herbicide, based on results from various studies.

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

Major adverse effects of dichlobenil observed are hepatocellular hypertrophy, increased liver weights, increased kidney weights, increased incidences of chronic progressive nephrosis, and effects on blood such as anemia. Dichlobenil did not show any clear reproductive toxicity, neurotoxicity and genotoxicity.

Although increased incidences of hepatocellular tumors were observed in rats in a two-year combined chronic toxicity/carcinogenicity study, a genotoxic mechanism was unlikely to participate in the tumor development. It was thus considered possible to establish a threshold dose in the assessment.

Dichlobenil, at the dose with maternal toxicity, caused supernumerary ribs in rat fetuses and external or visceral anomalies in rabbits.

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

The lowest no-observed-adverse-effect level (NOAEL) obtained in all the tests was 1 mg/kg bw/day in an one-year chronic toxicity study in dogs. FSCJ specified an acceptable daily intake (ADI) of 0.01 mg/kg bw/day by applying a safety factor of 100 to the NOAEL.