

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

Risk Assessment Report

Etobenzamide (Pesticides)

Food Safety Commission of Japan (FSCJ)
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ABSTRACT

FSCJ conducted a risk assessment of “etobenzamide” (CAS No. 79540-50-4), an anilide herbicide, based on results from various studies.

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

Major adverse effects of etobenzamide observed are: effects on the liver such as increased organ weights, hepatocellular hypertrophy, foci of hepatocellular alterations, and degeneration of renal tubular epithelial cells in the kidney of rats. Etobenzamide had no developmental toxicity or genotoxicity relevant to human health.

Significant increases in the incidence of hepatocellular tumors in male rats of the 10,000 ppm treated group were identified in carcinogenicity tests. Moreover, in the same group, increases in the total incidence of hepatocellular adenomas and carcinomas were observed. However, based on further studies and the genotoxic study, genotoxic mechanism was not likely to be involved in the hepatocellular tumor induction and therefore FSCJ concluded that it is possible to establish a threshold dose.

In a two- generation reproduction test of etobenzamide in rats, extension of mating period and delayed vaginal opening were observed.

Based on the various study results, only etobenzamide (parent compound) was included in a residue definition for dietary risk assessment in agricultural and fishery products.

The minimum value of the no-observed adverse effect level (NOAEL) was 4.4 mg/kg bw/day in a two year combined chronic/carcinogenicity study in rats. FSCJ specified an acceptable daily intake (ADI) of 0.044 mg/kg bw/day by applying a safety factor of 100 to the NOAEL.