

Ethoxysulfuron

Summary

Food Safety Commission of Japan

The Food Safety Commission of Japan (FSCJ) conducted a risk assessment of ethoxysulfuron (CAS No. 126801–58-9), a sulfonyleurea herbicide, based on summary reports submitted by the applicant and documents from the Australian Government. Major adverse effects of ethoxysulfuron observed were decreased body weight gain, chronic septal hepatitis of dogs, and decreased serum T3 and T4 levels. Ethoxysulfuron did not show any clear reproductive toxicity, developmental toxicity, and genotoxicity. Although increased incidences of uterine adenocarcinomas were observed in rats in a two-year combined chronic toxicity/carcinogenicity study of ethoxysulfuron, a genotoxic mechanism was unlikely to participate in the tumor development. It was thus considered possible to establish a threshold in the assessment. Based on the above results, only ethoxysulfuron (parent compound) was identified as the residue definition for dietary risk assessment in agricultural products. The lowest no-observed-adverse-effect level (NOAEL) obtained in all the tests was 5.60 mg/kg bw/day in a 90-day subacute toxicity study in dogs. FSCJ specified an acceptable daily intake (ADI) of 0.056 mg/kg bw/day by applying a safety factor of 100 to the NOAEL.

Conclusion in Brief

FSCJ conducted a risk assessment of ethoxysulfuron (CAS No. 126801–58-9), a sulfonyleurea herbicide, based on summary reports submitted by the applicant and documents from the Australian Government.

The data used in the assessment include fate in animals (rats), fate in plants (paddy rice and sugarcane), 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), and genotoxicity.

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

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

The lowest no-observed-adverse-effect level (NOAEL) obtained in all the tests was 5.60 mg/kg bw/day in a 90-day subacute toxicity study in dogs. FSCJ specified an acceptable daily intake (ADI) of 0.056 mg/kg bw/day by applying a safety factor of 100 to the NOAEL.