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

Risk Assessment Report

Foramsulfuron

(Pesticides)

Food Safety Commission of Japan (FSCJ)

June 2021

ABSTRACT

The FSCJ conducted a risk assessment of foramsulfuron (CAS No. 173159-57-4), a sulfonylurea herbicide, based on submitted documents.

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

Major adverse effects of foramsulfuron were decreased body weight, suppressed body weight gain and decreased food intake, all of which were only observed among dams in a developmental toxicity study in rabbits. No neurotoxicity, carcinogenicity, effect on fertility, teratogenicity or biologically significant genotoxicity was observed.

Based on these results, foramsulfuron (parent compound only) was identified as the relevant substance for the residue definition for dietary risk assessment in agricultural products.

The lowest no-observed-adverse-effect level (NOAEL) was 50 mg/kg bw per day in a developmental toxicity study in rabbits. The FSCJ specified an acceptable daily intake (ADI) of 0.5 mg/kg bw per day by applying a safety factor of 100 to this NOAEL.

Since there was no adverse effect likely to be elicited by a single oral administration of foramsulfuron, the FSCJ considered it unnecessary to specify an acute reference dose (ARfD).

Table 1. *Levels relevant to toxicological evaluation of foramsulfuron*

Species	Study	Dose (mg/kg bw per day)	NOAEL (mg/kg bw per day)	LOAEL (mg/kg bw per day)	Critical endpoints[1)]
Rat	90-day subacute toxicity study	0, 20, 200, 5 000, 20 000 ppm M: 0, 1.54, 15.4, 388, 1 570 F: 0, 1.81, 19.4, 475, 1 790	M: 1 570 F: 1 790	M: - F: -	M/F: No toxicity
	28-day subacute neurotoxicity study	0, 3 750, 15 000 ppm M: 0, 307, 1 210 F: 0, 362, 1 420	M: 1 210 F: 1 420	M: - F: -	M/F: No toxicity (No subacute neurotoxicity is observed.)
	Two-year combined chronic toxicity/ carcinogenicity study	0, 100, 600, 6 000, 20 000 ppm M: 0, 4.3, 25, 246, 849 F: 0, 5.6, 35, 339, 1 140	M: 849 F: 1 140	M: - F: -	M/F: No toxicity (No carcinogenicity is observed.)
	Two-generation reproductive toxicity study	0, 100, 1 230, 15 000 ppm PM: 0, 6, 75, 957 PF: 0, 9, 110, 1 370 F_1M: 0, 7, 88, 1 120 F_1F: 0, 10, 120, 1 490	Parent and offspring: PM: 957 PF: 1 370 F_1M: 1 120 F_1F: 1 490	Parent and offspring: PM: - PF: - F_1M: - F_1F: -	Parent and offspring: No toxicity (No effect on fertility is observed.)
	Developmental toxicity study	0, 5, 71, 1 000	Dams and Fetuses: 1 000	Dams and fetuses: -	Dams and fetuses: No toxicity (No teratogenicity is observed.)
Mouse	90-day subacute toxicity study	0, 64, 3 200, 6 400 ppm M: 0, 10.5, 498, 1 000 F: 0, 14.6, 822, 1 180	M: 1 000 F: 1 180	M: - F: -	M/F: No toxicity
	80-week carcinogenicity study	0, 40, 800, 8 000 ppm M: 0, 5.4, 109, 1 120 F: 0, 6.5, 134, 1 360	M: 1 120 F: 1 360	M: - F: -	M/F: No toxicity (No carcinogenicity is observed.)

Rabbit	Developmental toxicity study	0, 5, 50, 500	Dams: 50 Fetuses: 500	Dams: 500 Fetuses: -	Dams: Decreased body weight/ suppressed weight gain, decreased food intake Fetuses: No toxicity (No teratogenicity is observed.)
Dog	90-day subacute toxicity study	0, 10, 250, 1 000	M/F: 1 000	M/F: -	M/F: No toxicity
	One-year chronic toxicity study	0, 5, 100, 1 000	M/F: 1 000	M/F: -	M/F: No toxicity
ADI			NOAEL: 50 SF: 100 ADI: 0.5		
The critical study for setting ADI			Developmental toxicity study (rabbit)		

ADI, Acceptable daily intake; NOAEL, No-observed-adverse-effect level; SF, Safety factor
-: LOAEL could not be specified.
[1)] The adverse effect observed at LOAEL