MINISTRY OF FOOD AND DRUG SAFETY
National Institute
of Food and Drug Safety Evalution

Risk Assessment of Fosthiazate

Fosthiazate, an organophosphorous nematicide, is used to inhibit cholinesterase in soil pests in general, and applied on crops such as potato, tomato, and banana. In Korea, it was first registered in the form of emulsion in 1995, and its MRL is set at 0.05–0.5 mg/kg for 11 foodstuffs including chili pepper and garlic (MRLs for Pesticides in Foods, May 31, 2016).

The ADI of fosthiazate at 0.001 mg/kg bw/day was established by applying the safety factor 100 (differences between species and individual entities) to the NOAEL 0.1 mg/kg bw/day obtained from the repeated dose study on dogs conducted for one year. The rise in the level of glutamic-pyruvic transaminase was observed in oral administration on dogs at 0.5 mg/kg bw/day, while teratogenicity was not observed in the reproductive and developmental toxicity studies on rats. The NOAEL was set at 0.1 mg/kg bw/day, the concentration level where toxicity effect (inhibition of acetylcholinesterase in red blood cells and the brain) did not appear.

The intake amount of fosthiazate was calculated based on the results of the analysis of 2,082 samples of 52 foodstuffs including rice in the Monitoring of Agricultural Products in Korea (2011–2015) by the National Institute of Food and Drug Safety Evaluation. The results of the monitoring showed that fosthiazate was detected in two samples (carrot 0.024 mg/kg, cucumber 0.038 mg/kg); the pesticide level was below the LOQ, and thus, it was not detected in the rest of the samples. Concerning data lower than the LOQ, in case more than 60% of data were below the LOQ, estimation was made by applying 0 (non-detection) as the lower exposure limit or LOQ (upper exposure limit), according to the "evaluation of low level contamination of foods" recommended by the WHO. Food consumption was calculated through SAS 9.4 using the tertiary food code data from the KNHANES conducted for five

years (2010–2014). For the average weight of all age groups, 60 kg, the weight currently (as of 2016) being applied for establishment and revision of pesticide residue standards, was used. Concerning the average weights of different age groups, the data from KNHANES were used in applying 12.3 kg, 19.2 kg, 37.4 kg, 59.5 kg, 65 kg, and 58.3 kg to the 1–2 year group, 3–6 year group, 7–12 year group, 13–19 year group, 20–64 year group, and the group aged 65 years or above, respectively. Risk characterization was made by calculating the HI in consideration of the EDI calculated in the exposure assessment and the ADI, the safe level of human exposure.

In general, when HI is 1 or higher, the adverse effects of toxicity may be expected from the exposure, and when HI is lower than 1, adverse effect is not expected. The results of the risk assessment of fosthiazate in different age groups revealed HI of 0.2×10^{-3} (non-detection data LOQ applied), as shown in the table below, and that its concentration is within the safe level of human exposure.

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Table 1. ADI and HI of fosthiazate

Age	EDI (mg/person/day)		Average weight (kg)	EDI (mg/kg bw/day)		ADI (mg/kg bw/day)	HI	
	0	LOQ (mg/kg)		0	LOQ (mg/kg)		0	LOQ (mg/kg)
All	0.2×10^{-4}	4.0×10^{-3}	60	0.3×10^{-6}	0.1×10^{-3}		0.3×10^{-3}	0.067
1−2	0.4×10^{-5}	2.0×10^{-3}	12.3	0.3×10^{-6}	0.2×10^{-3}		0.3×10^{-3}	0.165
3−6	0.1×10^{-4}	2.6×10^{-3}	19.2	0.4×10^{-6}	0.1×10^{-3}		0.4×10^{-3}	0.136
7−12	0.1×10^{-4}	0.1×10^{-3}	37.4	0.3×10^{-6}	0.1×10^{-3}	0.001	0.3×10^{-3}	0.083
13−19	0.2×10^{-4}	3.4×10^{-3}	59.5	0.3×10^{-6}	0.1×10^{-3}		0.3×10^{-3}	0.058
20−64	0.2×10^{-4}	4.3×10^{-3}	65.0	0.3×10^{-6}	0.1×10^{-3}		0.3×10^{-3}	0.066
≥65	0.1×10^{-4}	3.9×10^{-3}	58.3	0.2×10^{-6}	0.1×10^{-3}		0.2×10^{-3}	0.066

Key words: Fosthiazate, Risk Assessment, Organophosphorus insecticide, ADI, Monitoring, Pesticide