

2016 SCIENTIFIC REPORT



MINISTRY OF FOOD AND DRUG SAFETY

National Institute
of Food and Drug Safety Evaluation

Risk Assessment of Phosalone

Phosalone is an organophosphorous pesticide not yet registered for domestic usage, but is used in other countries such as Australia, Belgium, and Canada on crops including almond, apple, apricot, cherry, grapes, peach, and pear. Its MRL in Korea is set at 0.1–10 mg/kg on 17 foodstuffs such as potato and chili pepper (MRLs for Pesticides in Foods, May 31, 2016).

The ADI of phosalone at 0.002 mg/kg bw/day was established by applying the safety factor 100 (differences between species and individual entities) to the NOAEL of 0.2 mg/kg bw/day obtained, in relation to the inhibition of activation of acetylcholinesterase in red blood cells, its representative toxicity endpoint, from the chronic toxicity and carcinogenicity studies on rats carried out for two years.

The intake amount of phosalone 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 result of the monitoring showed that the pesticide level was below the LOQ, and thus, phosalone was not detected in any 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. 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.

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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 phosalone in all age groups revealed HI between 0 (non-detection data 0 applied) and 0.011 (non-detection data LOQ applied), as shown in the table below, and that its concentration is within the safe level of human exposure.

Table 1. ADI and HI of phosalone

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	1.3×10^{-3}	60	0	0.2×10^{-4}	0.002	0	0.011

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