

CYPERMETHRINS (INCLUDING ALPHA- AND ZETA-CYPERMETHRIN) (118)

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EXPLANATION

Cypermethrin is a pyrethroid insecticide. The mode of action is non-systemic with contact and stomach action. The IUPAC name for cypermethrin is *(RS)- α -cyano-3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate* or *(RS)- α -cyano-3-phenoxy benzyl(1RS)-cis-trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate*. Cypermethrin was first evaluated by the JMPR in 1979 and periodic reviews were conducted in 2006 for toxicology and in 2008 for residues. Further evaluations for additional uses were conducted in 2009 and 2011.

The 2006 JMPR established an ADI of 0–0.02 mg/kg bw and an ARfD of 0.04 mg/kg bw. The 2008 JMPR established a residue definition for compliance with the MRL and dietary risk assessment for plant and animal commodities of *cypermethrin (sum of isomers)*. The residue is fat-soluble.

Cypermethrin was scheduled at the Fiftieth Session of the CCPR for evaluation of additional uses by the 2019 JMPR. The Meeting received information on GAP, residue trials and processing studies on ginseng.

METHODS OF RESIDUE ANALYSIS

The analytical method used for analysis of cypermethrin residue in fresh ginseng and the processed products (dried-, red ginseng, the water extracts) involved extraction with acetone or acetonitrile, partitioning with dichloromethane, clean-up using florisil and determination by GC-ECD. Procedural recovery tests were performed at three fortification levels ($n = 5$ at each level), 0.03–0.3 mg/kg for fresh ginseng and 0.06–0.6 mg/kg for the processed products. The mean recovery at each fortification level was in the range of 79–106% (RSDs, $\leq 10\%$). The LOQ values for cypermethrin were 0.03 mg/kg in fresh ginseng and 0.06 mg/kg in the processed products.

USE PATTERN

The Meeting received GAP information on ginseng from the Republic of Korea. The information is summarized in Table 1.

Table 1 Registered use of cypermethrin on ginseng in the Republic of Korea

Crop	Formulation	Application			PHI (days)
		Method	kg ai/hL	No.	
Ginseng	Emulsifiable concentrate (EC) 5%	Foliar application	0.0050	3	45

RESULTS OF SUPERVISED RESIDUE TRIALS ON CROPS

The Meeting received residue trials on ginseng conducted in the Republic of Korea. The detailed information are summarized in Table 2 as below.

CODEX Group	Commodity	Table No.
Group 016 Root and tuber vegetables	<u>Subgroup 016A Root vegetables</u> VR 0604 Ginseng	Table 2

Root and tuber vegetables

Ginseng

A total of nine residue trials on ginseng (Korean ginseng; *Panax ginseng* C.A. Mayer; 4- or 5-year-old ginseng) were conducted in the Republic of Korea in 2015 and 2016 [Kyung, K.S., 2018, Study No. 13162MFDS009]. Each trial consisted of three plots. An EC formulation of cypermethrin (5%) was applied to ginseng plants as a foliar application at rates of 0.0043–0.0050 kg ai/hL in 3 applications with re-treatment intervals of 8 to 10 days. The spray volumes ranged between 1700–2000 litres per hectare. Three replicate samples from three plots were collected at 45 days after the last application. Harvested ginseng roots were washed with water in a cleaning machine to remove adhering soil particles, and then stored at -20 °C until analysis. The maximum storage period of the samples (fresh and processed product) was 102 days.

Table 2 Residues in fresh ginseng following foliar application of cypermethrin in the Republic of Korea (Study No. 13162MFDS009)

Location, Year (Variety, Age of ginseng)	Application					DAL A	Commodity	Cypermethrin (mg/kg)*
	n	kg ai/hL	L/ha	kg ai/ha	Inter. days			
GAP: Korea	3	0.0050				45		
Korea Yeongju, 2015 (Korean ginseng, 4-year-old)	3	0.0044- 0.0047	1750- 1850	0.088- 0.093	10	45	Ginseng roots	<0.03, <0.03, <0.03
Korea Yeongju, 2016 (Korean ginseng, 5-year-old)**a	3	0.0049- 0.0050	1950- 2000	0.098- 0.10	8-10	45	Ginseng roots	<0.03, <0.03, <0.03
Korea Yeongju, 2016 (Korean ginseng, 5-year-old) ^a	3	0.0049- 0.0050	1950- 2000	0.098- 0.10	8-10	45	Ginseng roots	<0.03, <0.03, <0.03
Korea Geumsan, 2015 (Korean ginseng, 4-year-old)	3	0.0043- 0.0047	1700- 1850	0.085- 0.093	10	45	Ginseng roots	<0.03, <0.03, <0.03
Korea Geumsan, 2016 (Korean ginseng, 5-year-old)**b	3	0.0048- 0.0050	1900- 2000	0.095- 0.10	10	45	Ginseng roots	<0.03, <0.03, <0.03
Korea Geumsan, 2016 (Korean ginseng, 5-year-old) ^b	3	0.0047- 0.0049	1850- 1950	0.093- 0.098	10	45	Ginseng roots	<0.03, <0.03, <0.03
Korea Cheongju, 2015 (Korean ginseng, 4-year-old)	3	0.0047- 0.0048	1850- 1900	0.093- 0.095	10	45	Ginseng roots	<0.03, <0.03, <0.03
Korea Cheongju, 2016 (Korean ginseng, 5-year-old)**c	3	0.0047- 0.0049	1850- 1950	0.093- 0.098	10	45	Ginseng roots	<0.03, <0.03, <0.03
Korea Cheongju, 2016 (Korean ginseng, 5-year-old) ^c	3	0.0049- 0.0050	1950- 2000	0.098- 0.10	10	45	Ginseng roots	<0.03, <0.03, <0.03

EC (5%) formulation was applied.

* Three replicate samples, taken in three replicate plots of each trial, were analysed.

** Ginseng was treated previously, when the crop was 4-years-old, according to the Korean GAP.

^{a, b, c} The same letter means that the trials were not independent, due to the same trial sites and application dates.

FATE OF RESIDUES IN STORAGE AND PROCESSING*In processing*

The Meeting received information on the fate of cypermethrin residues during the processing of ginseng.

Ginseng (dried-, red ginseng, the water extracts)

Ginseng was treated three times with EC (5%) formulation at rates of 0.0043–0.0050 kg ai/hL at 8–10 day intervals. In all raw agricultural commodity samples (fresh ginseng, washed with water), cypermethrin concentrations were below the LOQ value (0.03 mg/kg), as shown in Table 2.

The washed ginseng was dried in hot air to produce dried ginseng (water content, < 14%) or steamed (65 °C) and dried in hot air to produce red ginseng (water content, < 14%). Water extracts of the dried and red ginseng were made by refluxing with water followed by evaporation of water to reach 72° Brix. A total of nine processing studies were conducted.

Table 3 Cypermethrin residues in ginseng processed products (Study No. 13162MFDS009)

Trial: Location, Year (Age of ginseng)	Processed commodity	Cypermethrin (mg/kg)*
Cypermethrin, <0.03 mg/kg in RAC (fresh ginseng)		
Korea, Yeongju, 2015 (4-year-old)	Dried ginseng	<0.06
	Red ginseng	<0.06
	Water extract of dried ginseng	<0.06
	Water extract of red ginseng	<0.06
Korea, Yeongju, 2016 (5-year-old)**	Dried ginseng	0.06
	Red ginseng	<0.06
	Water extract of dried ginseng	<0.06
	Water extract of red ginseng	<0.06
Korea, Yeongju, 2016 (5-year-old)	Dried ginseng	<0.06
	Red ginseng	<0.06
	Water extract of dried ginseng	<0.06
	Water extract of red ginseng	<0.06
Korea Geumsan, 2015 (4-year-old)	Dried ginseng	<0.06
	Red ginseng	<0.06
	Water extract of dried ginseng	<0.06
	Water extract of red ginseng	<0.06
Korea, Geumsan, 2016 (5-year-old) **	Dried ginseng	0.10
	Red ginseng	0.06
	Water extract of dried ginseng	<0.06
	Water extract of red ginseng	<0.06
Korea, Geumsan, 2016, (5-year-old)	Dried ginseng	0.08
	Red ginseng	0.06
	Water extract of dried ginseng	<0.06
	Water extract of red ginseng	<0.06
Korea, Cheongju, 2015 (4-year-old)	Dried ginseng	<0.06
	Red ginseng	<0.06
	Water extract of dried ginseng	<0.06
	Water extract of red ginseng	<0.06
Korea, Cheongju, 2016 (5-year-old) **	Dried ginseng	<0.06
	Red ginseng	<0.06
	Water extract of dried ginseng	<0.06

Trial: Location, Year (Age of ginseng)	Processed commodity	Cypermethrin (mg/kg)*
	Water extract of red ginseng	<0.06
Korea, Cheongju, 2016 (5-year-old)	Dried ginseng	<0.06
	Red ginseng	<0.06
	Water extract of dried ginseng	<0.06
	Water extract of red ginseng	<0.06

* Mean value of three analytical replicates

** Ginseng was treated previously, when the crop was 4-years-old, according to the Korean GAP.

APPRAISAL

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The 2006 JMPR established an ADI of 0–0.02 mg/kg bw and an ARfD of 0.04 mg/kg bw. The 2008 JMPR established a residue definition for compliance with the MRL and dietary risk assessment for plant and animal commodities of *cypermethrin (sum of isomers)*. The residue is fat-soluble.

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Methods of analysis

The analytical method used for analysis of cypermethrin residues in fresh ginseng and the processed products (dried-, red ginseng, the water extracts) involved extraction with acetone or acetonitrile, partitioning with dichloromethane, clean-up using florisil and determination by GC-ECD. Procedural recoveries ranged from 79–106% (RSDs ≤ 10%) and the LOQ values for cypermethrin were 0.03 mg/kg in fresh ginseng and 0.06 mg/kg in the ginseng processed products.

Stability of residues in stored analytical samples

The 2011 JMPR concluded that cypermethrin is stable for at least 18 months in frozen plant matrices of high water and high oil content. The residue sample storage intervals used in the field trials considered by the current Meeting were covered by the demonstrated stability period.

Results of supervised residue trials on ginseng

The critical GAP for cypermethrin on ginseng in the Republic of Korea is 3 foliar applications at a rate of 0.005 kg ai/hL with a 45 day PHI. Six independent trials conducted in the Republic of Korea matched the critical GAP. Cypermethrin residues in fresh ginseng were < 0.03 mg/kg (n = 6).

The Meeting estimated a maximum residue level of 0.03(*) mg/kg, a STMR of 0.03 mg/kg and a HR of 0.03 mg/kg for cypermethrin in ginseng.

Fate of residues during processing

The Meeting received information on the fate of cypermethrin residues during processing of ginseng. In these studies residues of cypermethrin in the raw agricultural commodity (fresh ginseng) were all less than LOQ. Therefore, the Meeting could not estimate processing factors for ginseng processed products.

The Meeting noted that in all the field trials matching GAP, fresh ginseng samples were washed and dried to produce dried ginseng, or steamed and dried to produce red ginseng. Residues of cypermethrin were measured in the dried and red ginseng and in their water extracts.

Cypermethrin residues in dried and red ginseng were < 0.06 (9), 0.06 (2), and 0.10 mg/kg (n = 12).

Cypermethrin residues in water extracts of dried and red ginseng were < 0.06 (12) mg/kg (n = 12).

The Meeting estimated a maximum residue level of 0.15 mg/kg, a STMR of 0.06 mg/kg and a HR of 0.10 mg/kg for cypermethrin in ginseng, dried including red ginseng. The Meeting estimated a maximum residue level of 0.06(*) mg/kg, a STMR of 0.06 mg/kg and a HR of 0.06 mg/kg for cypermethrin in ginseng, extracts.

RECOMMENDATIONS

On the basis of the data obtained from supervised trials, the Meeting concluded that the residue levels listed below are suitable for establishing maximum residue limits and for IEDI and IESTI assessments.

Definition of the residue for compliance with the MRL for plant and animal commodities: *cypermethrin (sums of isomers)*

Definition of the residue for dietary risk assessment for plant and animal commodities: *cypermethrin (sums of isomers)*

The residue is fat-soluble.

Table 1 Residue levels suitable for establishing maximum residue limits and for IEDI and IESTI assessments

CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
		New	Previous		
VR 0604	Ginseng	0.03(*)		0.03	0.03
DV 0604	Ginseng, dried including red ginseng	0.15		0.06	0.10
DM 0604	Ginseng, extracts	0.06(*)		0.06	0.06

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for cypermethrin is 0–0.02 mg/kg bw. The STMRs/STMR-Ps for food commodities estimated by the current Meeting did not affect the International Estimated Daily Intakes (IEDIs) for cypermethrin calculated by the 2011 JMPR. The Meeting concluded that long-term dietary exposure to residues of cypermethrin from uses considered by the JMPR is unlikely to present a public health concern.

Acute dietary exposure

The ARfD for cypermethrin is 0.04 mg/kg bw. The International Estimate of Short Term Intakes (IESTIs) for cypermethrin were calculated for the food commodities (raw and processed commodities) for which HRs/HR-Ps or STMRs/STMR-Ps were estimated by the present Meeting and for which consumption data were available. The results are shown in Annex 4 of the 2019 JMPR Report.

The IESTIs were 0% of the ARfD for children and the general population. The Meeting concluded that acute dietary exposure to residues of cypermethrin from the use considered by the present Meeting is unlikely to present a public health concern.

REFERENCES

Author	Study No.	Year	Study title
Kyung, K.S.	13162MFDS009	2018	Magnitude of cypermethrin residues in Ginseng and its processing products in Korea. Ministry of Food and Drug Safety (MFDS), Cheongju 28159, Republic of Korea