CHLOROTHALONIL (081)

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EXPLANATION

Chlorothalonil is a non-systemic fungicide first evaluated by JMPR in 1974 and a number of times subsequently. The latest JMPR review for chlorothalonil was conducted in 2009 (T) and 2010 (R). It was listed by the Forty-third Session of the CCPR for the evaluation of additional MRLs by the 2012 JMPR.

The residue studies on chicory, endive, spring onion, spinach, silverbeet (Swiss chard) and peas were provided by Australia, and data for banana were submitted by the manufacture for additional MRLs.

Method of residue analysis

Banana

Two methods were used for data collection: POPIT.MET.036.Rev02 (Broscolo, 2004) for the four trials conducted in 2005 and POPIT.MET.051.Rev02 (Marconi, 2004) for the four trials conducted in 2008. Brief descriptions of these methods follow.

POPIT.MET.036.Rev02

Samples are ground with dry ice and about 100 mL of sulphuric acid (1 mol/L per kg sample) is added. A 10 g sample is extracted with a solution of 50 mL acetone: 5 mol/L sulphuric acid (95:5 v/v) and homogenized. Sample purification makes use of gel permeation chromatography and extraction procedures using cyclohexane: ethyl acetate (1:1 v/v). Quantitation is by gas chromatography with an electron capture detector. The LOQ for this method was estimated to be 0.1 mg/kg.

POPIT.MET.051.Rev02

Samples are ground with dry ice and about 100 mL of sulphuric acid (1 mol/L per kg sample) is added. A 5 g sample is extracted with a solution of 50 mL acetone: 5 mol/L sulphuric acid (95:5 v/v) and homogenized. The sample is centrifuged and an aliquot of the resulting mixture is evaporated to a volume of 1–2 mL. The sample is partitioned several times between an aqueous solution of sodium chloride and toluene. The upper layer is adjusted to 4 mL with toluene. Quantitation is by gas chromatography with mass selective detection (GC/MSD), operating in single ion monitoring (SIM) mode. The LOQ for this method was estimated to be 0.01 mg/kg.

Vegetables [peas, silverbeet, spinach, spring onion, endive, chicory]

For the trials conducted in 2003, the analytical methods involved sample homogenization and extraction using acidified acetone. Sample clean-up made use of either gel permeation chromatography with a cyclohexane/ethyl acetate mixture as eluant, or partitioning into dichloromethane solvent. Sample analysis was by either GC/MSD or LC-MS/MS. Most of these trials reported an LOQ of 0.05 mg/kg, although for garden pea, the LOQ was 0.02 mg/kg.

For the trials conducted in 2006–2008, chlorothalonil residues were extracted using either acidified acetonitrile or acidified acetone. Sample clean up made use of SPE procedures. Analysis was by GC/MS/MS or GC/MSD(SIM) and resulted in LOQs of 0.01 or 0.05 mg/kg.

USE PATTERN

Chlorothalonil is a non-systemic protectant fungicide. The Meeting received the following uses involving foliar spray applications prior to harvest.

Table 1 List of additional registered uses of chlorothalonil

Crop	Country	Application details							
		Form	Type	kg ai/ha	kg ai/hL	L/ha	No.	Retreatment interval (RTI) in days	Pre harvest interval (PHI) in days
Banana	Brazil	SC 50%	foliar spray (ground + aerial)	1	0.2	500			0
Beetroot	Australia	SC 50%	foliar spray	1.66			4	7	7
Peas	Australia	SC 50%	foliar spray	1.3				7	7 [a]
Spinach	Australia	SC 50%	foliar spray	1.66			4	7	7
Swiss chard	Australia	SC 50%	foliar spray	1.66			4	7	7
Onion, spring	Australia	SC 50%	foliar spray	1.66				14	14
Onion, spring	United Kingdom	SC 40%	foliar spray	1	0.5	200	2		14
Chicory	Australia	SC 50%	foliar spray	0.75			2	7	7
Endive	Australia	SC 50%	foliar spray	1.66				7	1

[a] No feeding or grazing allowed

RESIDUES RESULTING FROM SUPERVISED TRIALS IN CROPS

Table 2 Chlorothalonil residues in bananas following foliar application [a]

Banana Year Variety	Number of applications	Rate (kg ai/ ha)	Water Volume (L/ha)	RTI (days)	PHI (days)	Chlorothalonil Residue (mg/kg)			Author, Date Study No Trial Ref No.
						Whole Fruit	Pulp	Pulp/whole fruit ratio [b]	
Brazil 2008 Nanica	6	1.08	400	14	0 3 5 7 10	<u>1.8</u> 1.2 1.4 1.2 1.5	0.09 <u>0.13</u> 0.13 0.09 0.06	0.05 0.11 0.093 0.075 0.040	Lopez 2009 M08011 LZF1
	4	1.0	1000	15	0 3 5 7 10	1.8 0.54 0.83 0.63 0.30	0.04 0.02 0.03 0.02 0.02	0.022 0.037 0.036 0.032 0.067	Lopez 2009a M08005 LZF1
Brazil 2008 Pacovan	6	1.08	400	14	0 3 5 7 10	1.2 <u>1.4</u> 1.1 0.75 1.1	<u>0.07</u> 0.04 0.05 0.04 0.03	0.058 0.029 0.045 0.053 0.027	Lopez 2009 M08011 LZF2
	4	1.0	1000	15	0 3 5 7 10	0.84 0.55 0.16 0.35 0.08	0.03 0.02 0.01 0.01 < 0.01	0.036 0.036 0.063 0.029 0.13	Lopez 2009a M08005 LZF2
Brazil 2008 Nanica	6	1.08	400	14	0 3 5 7 10	0.43 0.44 0.58 0.26 0.36	0.04 <u>0.07</u> 0.03 0.02 0.02	0.093 0.16 0.052 0.077 0.056	Lopez 2009 M08011 JJB1
	4	1.0	1000	15	0 3 5	0.49 0.31 0.24	< 0.01 0.02 0.01	0.020 0.065 0.042	Lopez 2009a M08005

Banana Year Variety	Number of applications	Rate (kg ai/ ha)	Water Volume (L/ha)	RTI (days)	PHI (days)	Chlorothalonil Residue (mg/kg)			Author, Date Study No Trial Ref No.
						Whole Fruit	Pulp	Pulp/whole fruit ratio [b]	
					7 10	0.59 0.59	0.03 0.03	0.051 0.051	JJB1
Brazil 2008 Nanica	6	1.08	400	14	0 3 5 7 10	0.34 0.18 0.13 0.09 0.18	0.05 0.02 0.02 0.01 0.02	0.15 0.11 0.15 0.11 0.11	Lopez 2009 M08011 JJB2
	4	1.0	1000	15	0 3 5 7 10	0.13 0.20 0.13 0.13 0.08	0.01 0.01 0.02 < 0.01 0.01	0.077 0.050 0.15 0.077 0.13	Lopez 2009a M08005 JJB2
Brazil 2005 Nanica	6	1.0	500	10	0 3 7 10 15	0.28 0.25 0.17 0.10 < 0.10	- - - - -		Fukimoto 2011 M04027 JJB
Brazil 2005 Nanicão	6	1.0	500	10	0 3 7 10 14	7.8 10 8.5 8.7 7.8	- - - - -		Fukimoto 2011 M04027 LZF1
Brazil 2005 Maça	6	1.0	500	10	0 3 7 10 14	0.11 0.20 0.24 < 0.10 0.12	- - - - -		Fukimoto 2011 M04027 LZF2
Brazil 2005 Caturra	6	1.0	500	10	0 3 7 10 15	< 0.10 0.11 < 0.10 < 0.10 < 0.10	- - - - -		Fukimoto 2011 M04027 DMO

[a] 4 apps could not be considered for estimation of the maximum residue levels because the trials conducted with 4 and 6 application at one site were not independent and the latter ones resulted in higher residues.

[b] Mean of pulp/whole fruit ratios: 0.071.

Table 3 Chlorothalonil residues in spring onions following foliar application (Gaw,2003; Adams, 2008)

Year Variety	Number of applications	Rate (kg ai/ ha)	Water Volume (L/ha)	RTI (days)	PHI (days)	Chlorothalonil Residue (mg/kg)
						Whole Onion
Walkamin, QLD 2001 Zelda	4	1.66	220	7	14	2.8
Naracoorte, SA 2001 Straight leaf	4	1.66	318.5	7	14	0.44
Spalford, TAS 2001 -	4	1.66	280	7	14	0.95
Saint Kilda, SA 2007 --	2	1.66		14	7 14 21	2.1 1.2 0.33
Pearcedale, Vic 2007 Javelin	2	1.66		14	7 15 22	1.4 0.13 0.06

Table 4 Chlorothalonil residues in chicory following foliar application (Allen, 2009)

Chicory Year Variety	Number of applications	Rate (g ai/ ha)	Water Volume (L/ha)	RTI (days)	PHI (days)	Chlorothalonil Residue (mg/kg)
						Whole Chicory
Vic 2007 Devil cat	2	748	253	7	0 1 3 7	65.78 41.78 34.59 4.37

Table 5 Chlorothalonil residues in endive following foliar application (Allen, 2009)

Endive Year Variety	Number of applications	Rate (g ai/ ha)	Water Volume (L/ha)	RTI (days)	PHI (days)	Chlorothalonil Residue (mg/kg)
						Whole Endive
Vic 2008 Ski	2	748	253	7	0 1 3 7	51.44 59.13 8.19 6.56

Table 6 Chlorothalonil residues in spinach following foliar application (Wells 2008; Dal Santo, 2003)

Spinach Year Variety	Number of applications	Rate (kg ai/ ha)	Water Volume (L/ha)	RTI (days)	PHI (days)	Chlorothalonil Residue (mg/kg)
						Whole Spinach
Waterloo, SA 2001 Balero	4	0 1.67	0 400	0 7	- 0 7 14	<0.05 3.0 2.8 1.9
Forth Tasmania 2002 Bocane	4	0 1.67	0 230	0 7	- 0 7 14 21	0.17 125 38.1 10.3 23.0
Clyde, VIC 2008 Spalding	4	1.656	800	7 7	0 1 3 NA	70.6 44.3 41.8 NA
Waterloo Corner, SA 2008 Parrot	4	1.656	500	7	0 1 2 7	107 75.6 102 66.3

Table 7 Chlorothalonil residues in Silverbeet (Swiss chard) following foliar application (Wells, 2008)

Silverbeet Year Variety	Number of applications	Rate (g ai/ ha)	Water Volume (L/ha)	RTI (days)	PHI (days)	Chlorothalonil Residue (mg/kg)
						Whole Silverbeet
Clyde, VIC 2008 Success	4	1656	800	7	0 1 3 7	<0.05 39.1 36.5 <u>19.4</u>
Waterloo Corner, SA 2008 Terranova Fordhook Giant	4	1656	1000	7	0 1 4 7	51.3 56.0 29.2 <u>16.0</u>
Mangrove Mtn., NSW 2008 Isabelle	4	1656	800	7	0 1 3 7	15.7 12.6 14.2 <u>8.5</u>

Table 8 Chlorothalonil residues in peas (with pods and succulent) following foliar application (Dal Santo, 2003; Hall, 2003)

Location Year Variety	Crop Variety	Number of applications	Rate (kg ai/ ha)	RTI (days)	PHI (days)	Chlorothalonil Residue (mg/kg)	
						Pods	Vines
Wanneroo WA 2002	Garden Pea Massey	4	1.3	7	0 7 14	12.1 <u>7.4</u> 3.5	63.7 78.5 54.6
Wanneroo W.A 2002 Trials not independent	Garden Pea Massey	4	1.3	7	0 7 14 Mean:	9.2 <u>3.3</u> 1.4 5.4	48.4 40.9 28.5
York, WA 2002	Garden Pea Green Feast	4	1.3	7	0 7 14	12.7 <u>5.9</u> 0.10	70.4 27.3 33.9
York, WA 2002 Trials not independent	Garden Pea Green Feast	4	1.3	7	0 7 14 Mean:	17.8 <u>8.7</u> 0.09 7.3	85.9 59.4 14.1
Murray Bridge S.A 2001	Snow Pea* Sumo	4	1.3	7 7	0 7	9.2 <u>2.5</u>	-- --
Cuprona, TAS 2001	Snow Pea* --	4	1.22	7 7	0 7	7.9 <u>5.1</u>	-- --

* Greenhouse grown.

Table 9 Chlorothalonil residues in beetroot following foliar application (Allen, 2009)

Beetroot Year Variety	Number of applications	Rate (kg ai/ ha)	Water Volume (L/ha)	RTI (days)	PHI (days)	Chlorothalonil Residue (mg/kg)
						Whole Beetroot
Cowra, NSW 2001 NA	4	1.66 1.66	340 340	7 7	0 7	<0.05 <u><0.05</u>
Hope Valley, WA 2001 NA	4	1.28 1.28	300-320 300-320	7 7	0 7	<0.05 <u><0.05</u>
Waterloo SA, 2001 NA	4	1.66 1.66 1.66 1.66	400 400 400 400	7 7 7 7	0 7 14 21	0.71 <u>2.1</u> 0.58 0.86

Residues in animal commodities

Pea vines are considered livestock feedstuffs. However, pea vines will not be fed according to the following label restriction for beans, peanuts, and peas: "Do not graze livestock on treated crops."

Because there are no new livestock feedstuffs resulting from the new crop uses, the dietary burden and estimates of residues in animal commodities provided by the 2010 JMPR remain unchanged.

APPRAISAL

Chlorothalonil (tetrachloroisophthalonitrile) was most recently evaluated by the JMPR in 2009 for toxicology and in 2010 for residues. For the parent compound, an ADI of 0–0.02 mg/kg bw and an ARfD of 0.6 mg/kg bw were established. In addition, the Meeting set an ADI of 0–0.008 mg/kg bw and an ARfD of 0.03 mg/kg bw for the metabolite SDS-3701.

The 2010 JMPR recommended the following residue definition for chlorothalonil:

Definition of the residue for compliance with MRL for plant commodities: *chlorothalonil*

Definition of the residue for estimation of dietary intake for plant commodities:

chlorothalonil

SDS-3701 (2,5,6-trichloro-4-hydroxyisophthalonitrile), all considered separately.

Definition of the residue for compliance with MRL and for estimation of dietary intake for animal commodities: *SDS-3701 (2,5,6-trichloro-4-hydroxyisophthalonitrile).*

The 2010 JMPR estimated maximum residue levels for numerous commodities, which were adopted as Codex MRLs by the Codex Alimentarius Commission in 2011. The compound was listed by the Forty-third Session of the CCPR for the review of additional MRLs. The 2012 JMPR received residue data for banana, chard, chicory, endive, spring onion, spinach, and peas.

Methods of residue analysis

The Meeting received information on the analytical methods used in the chlorothalonil field trials for bananas and vegetables. For banana, the samples were extracted with acidified acetone. After clean up, the residues were determined by GC-ECD with a resulting LOQ of 0.1 mg/kg in the trials from 2005. The trials conducted in 2008 made use of similar extraction and sample clean-up, together with GC/MSD analysis to obtain a LOQ of 0.01 mg/kg. Mean recoveries of 74–104% were reported in banana whole fruit and pulp samples spiked at the following levels: 0.01, 0.1, 4.0, and 10 mg/kg. Similar methods were used in the analysis of vegetables, with reported LOQs ranging from 0.01 to 0.05 mg/kg. Analytical methods used in the reported studies made appropriate use of sulphuric acid during sample homogenization to avoid degradation of chlorothalonil residues.

Stability of residues in stored analytical samples

No new information on storage stability was submitted. Detailed information from the 2010 JMPR showed that chlorothalonil residues are stable (> 70% remaining) in frozen storage for up to 12 months in most commodities: peaches, strawberries, oranges, potatoes, carrots, onions, cabbages, leeks, lentils, tomatoes, melons, sugar beet and barley forage.

The periods of demonstrated stability cover the frozen storage intervals in the residue studies.

Results of supervised residue trials on crops

The 2010 JMPR noted that metabolite SDS-3701 is found at negligible levels following direct crop treatments. In follow crops or after processing, the contribution of SDS-3701 should be accounted for in a separate dietary intake analysis, reflecting its different toxicological endpoint from chlorothalonil. Neither banana nor chard have processed commodities or are livestock feedstuffs. These commodities are not expected to increase the contribution of SDS-3701 included in the analysis conducted in 2010.

The OECD calculator was used as a tool in the estimation of the maximum residue level from the selected residue data set obtained from trials conducted according to proposed GAP. As a first step, the Meeting reviewed all relevant factors related to each data set in arriving at a best estimate of the maximum residue level using expert judgement. Then, the OECD calculator was employed. If the statistical calculation spreadsheet suggested a different value from that recommended by the JMPR, a brief explanation of the deviation was provided.

Bananas

In Brazil, chlorothalonil is registered for the use on banana at a rate of 1 kg ai/ha, a retreatment interval of 15 days, and a PHI of 0 days. Eight supervised field trials were conducted in Brazil. In four trials, whole fruit and pulp data were collected following 4 and 6 applications at the GAP rate. In the four other trials, only whole fruit data were collected after 6 applications at the GAP rate.

Chlorothalonil residues in whole fruits were (n=8): 0.11, 0.24, 0.28, 0.34, 0.59, 1.4, 1.8, and 10 mg/kg. In the pulp, residues were (n=4): 0.05, 0.07 (2), and 0.13 mg/kg. The mean of the ratios of the residue levels between the pulp and whole fruit in trials where both values were determined, was 0.071 (n=40).

Based on the data for whole fruits treated according to Brazilian GAP, the Meeting estimated a maximum residue level of 15 mg/kg for chlorothalonil in banana (whole fruit). Using the pulp/whole fruit ratio, the Meeting estimated an STMR value of 0.033 mg/kg (0.47 × 0.071) and an HR value of 0.71 mg/kg (10 × 0.071) for chlorothalonil in banana pulp.

Spring onion

Supervised trials data were available for spring onion from Australia.

In Australia, GAP for spring onion allows the use of chlorothalonil at 1.7 kg ai/ha with a 14-day retreatment interval and a 14-day PHI.

In five spring onion trials in Australia matching GAP, chlorothalonil residues in spring onion were (n=5): 0.13, 0.44, 0.95, 1.2, and 2.8 mg/kg.

Following recommendations from the 2010 JMPR, there is an existing spring onion MRL of 10 mg/kg, based on two applications at a rate of 1 kg ai/ha and a 14-day PHI, and four trials from the United Kingdom. The Meeting agreed that the existing MRL accommodates the GAP used in Australia.

Leafy vegetables

Supervised trial data were available for chard, chicory, endive, and spinach.

Chard (Silverbeet)

In Australia, chlorothalonil is registered for use on chard for up to 4 treatments at a rate of 1.7 kg ai/ha, with a PHI and a retreatment interval of 7 days. Three supervised field trials are available at this GAP from Australia.

Rank-order chlorothalonil residues in Swiss chard were (n=3): 8.5, 16, and 19 mg/kg.

The Meeting estimated a maximum residue level of 50 mg/kg for chlorothalonil in/on chard, an STMR value of 16 mg/kg, and an HR value of 19 mg/kg.

Chicory

In Australia, GAP for chicory specifies the use of chlorothalonil with a maximum of two foliar applications at 0.75 kg ai/ha, a 7-day retreatment interval, and a 7-day PHI.

One trial matching GAP from Australia was submitted, showing a residue of 4.4 mg/kg chlorothalonil.

The Meeting agreed that one trial is insufficient to base maximum residue estimates for chicory.

Endive

In Australia, GAP for endive specifies the use of chlorothalonil with a maximum of two foliar applications at 0.75 kg ai/ha, a 7-day retreatment interval, and a 7-day PHI.

One trial matching GAP from Australia was submitted, showing a residue of 6.6 mg/kg chlorothalonil.

The Meeting agreed that one trial is insufficient to base maximum residue estimates for endive.

Spinach

In Australia, GAP for spinach allows the use of chlorothalonil with a maximum of four foliar applications at 1.7 kg ai/ha, a 7-day retreatment interval, and a 7-day PHI.

Four trials matching GAP were available from Australia.

Rank-order chlorothalonil residue concentrations in spinach were: 2.8, 38, 42, and 66 mg/kg.

The Meeting agreed that four trials are insufficient to base maximum residue estimates for spinach.

Peas (pods and succulent = immature seeds)

Supervised trials data were available for garden and snow peas.

In Australia, GAP for peas allows the use of chlorothalonil with four foliar applications at 1.3 kg ai/ha, a 7-day retreatment interval, and a 7-day PHI.

A total of four trials on garden peas and two trials on snow peas were submitted from Australia. However, the Meeting noted that the garden pea trials were not independent; hence, only two trials match GAP for garden peas and snow peas, respectively.

Chlorothalonil residue concentrations in garden peas were: 5.4 and 7.3 mg/kg.

Chlorothalonil residue concentrations in snow peas were: 2.5 and 5.1 mg/kg.

The Meeting determined that insufficient trials were available to support maximum residue estimates for peas.

Beetroot

In Australia, chlorothalonil is registered for use on beetroot for up to 4 treatments at a rate of 1.7 kg ai/ha, with a PHI and retreatment interval of 7 days. Supervised field trials are available at this GAP.

A total of three trials on beetroot were conducted in Australia according to GAP.

Rank-order chlorothalonil residues in beetroot were (n=3): < 0.05 (2), and 2.1 mg/kg.

The Meeting determined that insufficient trials were available to support maximum residue estimates for beetroot.

RECOMMENDATIONS

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

Definition of the residue (for compliance with MRL) for plant commodities: *chlorothalonil*

Definitions of the residue (for estimation of dietary intake) for plant commodities:

Chlorothalonil.

SDS-3701 (2,5,6-trichloro-4-hydroxyisophthalonitrile), all considered separately

The residue is not fat-soluble.

Commodity		MRL Recommendation, mg/kg		STMR, mg/kg	HR, mg/kg
CCN	Name	New	Previous		
FI 0327	Banana	15	0.01* [a]	Chlorothalonil: 0.033 [b]	Chlorothalonil: 0.71 (Note 2)
VL 0464	Chard	50		Chlorothalonil: 16	Chlorothalonil: 19

[a] Based on bagged bananas.

[b] For banana pulp.

DIETARY RISK ASSESSMENT

Long-term intake

The ADI for chlorothalonil is 0–0.02 mg/kg bw. The International Estimated Daily Intakes (IEDI) for chlorothalonil was estimated for the 13 GEMS/Food cluster diets using the STMR or STMR-P values estimated by the current Meeting in addition to those determined by the 2010 JMPR. The results are shown in Annex 3 of the 2012 JMPR Report. The IEDI ranged from 8–50% of the maximum ADI. The Meeting concluded that the long-term intake of residues of chlorothalonil, from uses that have been considered by the JMPR, is unlikely to present a public health concern.

Short-term intake

The ARfD for chlorothalonil is 0.6 mg/kg bw. The International Estimated Short Term Intake (IESTI) for chlorothalonil was calculated for the plant commodities for which STMRs and HRs were estimated (banana and chard). The results are shown in Annex 4 of the 2012 JMPR Report. The IESTI calculated for chlorothalonil represented 7–70% of the ARfD. The Meeting concluded that the short-term intake of residues of chlorothalonil, from uses that have been considered by the JMPR, is unlikely to present a public health concern.

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