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SCIENTIFIC DATA REVIEWS  
EPA SERIES 361

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

1/25/2001

MEMORANDUM

**SUBJECT:** Clethodim (PC Code: 121011) in/on Tuberous and Corm Vegetables (1C Crop Subgroup). DP Barcode: D271789. MRID 43757704.

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**THRU:** Stephen Dapson, Branch Senior Scientist *Stephen C. Dapson*  
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Health Effects Division (7509C) *02/01/2001*

**TO:** Joanne Miller, PM Team # 23  
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In a previous review (PP#7F04873, D240302, M. Xue, 09/07/2000), HED requested that Valent conduct four additional potato field trials in Regions I (1), V (1), IX (1) and XI (1) for a permanent tolerance petition for the residues of clethodim and its metabolites in/on the Tuberous and Corm Vegetables Subgroup(Crop Subgroup 1-C). HED also recommended that a tolerance of 1.0 ppm for the combined residues of clethodim and its metabolites be established on the Tuberous and Corm Vegetables Subgroup(Crop Subgroup 1-C) as a conditional registration.

Valent U.S.A. Corporation conducted five potato field trials (MRID 43757704) in CO (1), ID (1), MA (1), ND (1) and WA (1) in 1994. The five potato field trial data were submitted on 08/01/95. However, on 09/8/95, Valent requested to withdraw the five potato field trial data for the use of clethodim on potatoes (PP#5F4572/5H5729, D219077, J. Morales, 02/06/96). In response to deficiencies cited in HED's review (D240302, M. Xue, 09/07/2000), Valent U.S.A. Corporation now requests the five potato field trial data be included in the tolerance petition for the residues of clethodim and its metabolites in/on the Tuberous and Corm vegetables (1C Crop Subgroup 1-C). Therefore, the five potato field trial data are evaluated in this review.

### **Conclusions:**

1. Based on the submitted field trial data, a revised Section B/label must be submitted which specifies a maximum of 2 applications at a minimum retreatment interval of 14 days for potatoes.
2. The submitted field trial data for potatoes are adequate to satisfy the data requirement described in OPPTS 860.1500. Five potato field trials were conducted in regions I (1), V (1), IX (1), and XI (2) [i.e., CO (1), ID (1), MA (1), ND (1), and WA (1)]. All crops were treated two times with Select® 0.94 EC (also known as Prism) by ground spray application of 0.25 lb ai/A for a total application of 0.5 lb ai/A/season (1X) at 13 - 16 day intervals, and 31 days prior to harvest. The combined residues of DME and DME-OH ranged from <0.1 ppm (the LOD) to 0.70 ppm which support the proposed tolerance at 1.0 ppm for the Tuberous and Corm Vegetables (1C Crop Subgroup).
3. The method RM-26B-3 (a modification of RM-26B-2) was validated for potatoes at fortification levels of 0.2 ppm, 0.5 ppm, and 1.0 ppm. Recoveries (68 % - 91.7%) were within the acceptable range at all fortification levels tested. The common moiety method RM-26B-3 for the determination of clethodim and its metabolites in potatoes is acceptable for data collection and enforcement purposes. Both methods (RM-26B-2 and RM-26B-3) have been forwarded to FDA as enforcement methods for inclusion in PAM II.
4. The storage stability data are adequate to support potato field trial data. Potato and its processed commodities were stored frozen for up to 6 months before analysis. Storage stability data showed that residues of clethodim and its metabolites are stable up to six months under frozen condition in potatoes and its processed commodities.

### **Recommendation:**

Pending submission of a revised Section B/label as specified in Conclusion 1, there are no residue chemistry data requirements that would preclude the establishment of a permanent tolerance for residues of clethodim and its metabolites in the Tuberous and Corm Vegetables Subgroup (Crop Subgroup 1-C). HED continues to recommend that the tolerance level for the combined residues of clethodim and its metabolites be established at 1.0 ppm for the Tuberous and Corm Vegetables Subgroup (Crop Subgroup 1-C).

### **Detailed Considerations:**

#### **Proposed Use**

Select® is intended to selectively provide post-emergence control of annual and perennial grasses. Apply Select® 0.94EC at the dose rate of 0.06-0.25 lb ai/A (8-34 fl oz/A)/treatment

with no more than 0.5 lb ai/A/season (68 fl oz/A/season). Apply Select® 2EC at the dose rate of 0.06-0.25 lb ai/A (4-16 fl. oz/A)/treatment with no more than 0.5 lb ai/A/season (32 fl oz/A/season). The PHI is 30 days for potato. The spray interval is not specific but is dependent on the rate of kill (7-14 days), rate of emergence of new growth (application 2-3 weeks after emergence or to specific height), irrigation patterns, cultivation patterns, use of other herbicides, and degree of stress induced by adverse conditions. Section B provides general use directions specifying reapplication in 2-3 weeks. A crop oil concentrate containing at least 15% emulsifier at 1% v/v to finished spray volume is to be used as an adjuvant with either formulation. The minimum application volume is 3 gal/A by air and 5 gal/A by ground for either formulation. Maximum spray volumes are 10 gal/A by air and 40 gal/A by ground with nozzle pressure between 30-60 psi. The products are not to be applied by any irrigation system. There are no specific plant-back intervals or directions for rotational crops except that when Select® 0.94 EC or Select® 2 EC is used on fallow ground only clethodim registered use crops may be planted within 30 days of application.

#### HED Comments/Conclusion:

Based on the submitted field trial data, a revised Section B/label must be submitted which specifies a maximum of 2 applications at a minimum retreatment interval of 14 days for potatoes.

#### Method Validation:

Method RM-26B-3 (a modification of RM-26B-2) was used for the analysis of potato samples at the limit of detection (LOD) of 0.1 ppm. The analyses were conducted in Valent Technical Center, Dublin, CA. Method RM-26B-3 measures total residues of clethodim as two common moieties in plant or animal tissues by gas chromatography. The method cannot distinguish between clethodim and sethoxydim. The method involves extraction with methanol and/or water, followed by cleanup with alkaline precipitation and acid back extraction into dichloromethane. An alkaline hydrogen peroxide oxidation converts sulfides and sulfoxides to sulfones and then to dicarboxylic acids. The dicarboxylic acids are derivatized to dimethyl esters which are partitioned into dichloromethane; the measurement of the pentanedioic acid dimethyl esters (DME sulfone and DME-OH sulfone) is by (GC-FID) in the sulfur mode. Quantitation is from a standard curve using DME and DME-OH and the total residue is expressed as clethodim equivalents. For recovery studies the samples may be fortified with clethodim, clethodim sulfoxide, or 5-OH clethodim sulfone, common metabolites of clethodim in plants. Calculations were provided to show the method of conversion of detected DME or DME-OH to clethodim, clethodim sulfoxide, or 5-OH clethodim sulfone.

Recovery samples were analyzed concurrently at fortification levels of 0.2 ppm, 0.5 ppm, and 1.0 ppm for potato tubers, and 0.5 ppm for potato wet peel, dry peel, chips, and flakes. The fortification levels and recovery data are reported in Table 1.

Table 1. Concurrent Method recovery of clethodim(CS), clethodim sulfoxide (CSO), and 5-OH clethodim sulfone (5-OH CSO<sub>2</sub>) from fortified potato samples.

Matrix	Fortification Level (ppm)	(number of analyses) Range of Recoveries			
		CSO (ppm)	% Recovery	5-OH CSO <sub>2</sub> (ppm)	% Recovery
Tubers	1.0	0.764, 0.742	76.4, 74.2	0.685, 0.771	68.5, 77.1
	0.50	0.399	79.8	0.407	81.4
	0.20	0.166	83.4	0.183	91.7
Wet peel	0.5	0.386	77.2	0.333	66.6
Dry Peel	0.5	0.416	83.2	0.338	67.6
Chips	0.5	0.469	93.8	0.529	82.2
Flakes	0.5	0.432	86.4	0.447	89.4

HED Comments/Conclusion:

The method RM-26B-3 (a modification of RM-26B-2) was validated for potatoes at fortification levels of 0.2 ppm, 0.5 ppm, and 1.0 ppm. Recoveries (68 % - 91.7%) were within the acceptable range at all fortification levels tested. The common moiety method RM-26B-3 for the determination of clethodim and its metabolites in potatoes is acceptable for data collection and enforcement purposes. Both methods (RM-26B-2 & RM-26B-3) have been forwarded to FDA as enforcement methods for inclusion in PAM II.

Storage Stability

Storage stability studies were conducted for potatoes, potato wet peel, dry peel, flakes and chips in this submission. Weathered samples of potato and its processed commodities were stored frozen for up to 6 months before analysis. Storage stability data showed that potatoes and its processed commodities are stable up to six months under frozen condition (see Table 2).

Table 2. Storage stability of clethodim residues in potatoes and potato processed commodities.

Commodities	Storage Sample Days	Residue Found (ppm)		Fresh Fortification Recovery (%)		Corrected Residues (ppm)	
		DME	DME-OH	DME	DME-OH	DME	DME-OH
Potato tubers	0	0.57	0.35	76.4	68.5	0.75	0.51
		0.61	0.38			0.80	0.55
		0.60	0.41			0.79	0.60
	205	0.72	0.37	101	81.7	0.71	0.45
		0.71	0.35			0.70	0.43
		0.68	0.36			0.69	0.44
Wet peel	0	0.26	0.12	77.2	66.6	0.34	0.18
	180	0.28	0.12	88.2	82.3	0.32	0.15
Dry peel	0	1.9	0.81	83.2	67.6	2.28	1.19
	180	2.5	0.97	102	95.2	2.45	1.02
Flakes	0	1.6	0.60	86.4	89.4	1.86	0.67
	189	1.6	0.64	87.8	75.7	1.82	0.84
Chips	0	0.99	0.36	93.8	82.2	1.05	0.44
	189	0.86	0.28	92.8	78.7	0.92	0.35

Data from MRID 43757704

HED Comments/Conclusion:

The storage stability data are adequate to support potato field trial data. Potato and its processed commodities were stored frozen for up to 6 months before analysis. Storage stability data showed that residues of clethodim and its metabolites are stable up to six months under frozen condition in potatoes and its processed commodities.

Residue Data:

Five potato field trials were conducted in regions I (1), V (1), IX (1), and XI (2) [i.e., CO (1), ID (1), MA (1), ND (1), and WA (1)]. The residue data are reported in:

MRID 437577-04. Lai, J.C. (1996) Magnitude of Clethodim Residues in Potatoes - Tubers and Processed Parts (1995). Valent U.S.A. Corporation, Valent Technical Center, 6560 Trinity Court, Dublin, CA 94568. Laboratory ID. V-10908, June 29, 1995. 1 Volume. pp 427

All crops were treated two times with Select® 0.94 EC (also known as Prism) by ground spray

application of 0.25 lb ai/A for a total application of 0.5 lb ai/A/season (1X) at 13 - 16 day intervals, and 31 days prior to harvest. The spray volume for the trials was between 16.6 and 21.7 gallons per acre (GPA). The spray included a tank-mixed crop oil concentrate at 1% v/v of the final spray. The residue data for potatoes are summarized in Table 3.

Table 3. Residues of Clethodim and its Metabolites in Potato Tubers Reflecting Treatment with Select 0.94 EC and a 30 day PHI

State	Interval (days) between application	ppm as Clethodim		
		DME	DME-OH	Total
ID	16	0.16, 0.13	0.12, 0.11	0.28, 0.24
ND	14	0.42, 0.42	0.18, 0.19	0.60, 0.61
CO	13	0.35, 0.45	0.18, 0.25	0.53, 0.70
WA	14	0.11, <0.1	<0.1, <0.1	0.16, <0.1
ME	13	0.23, 0.14	0.21, 0.15	0.44, 0.29

HED Comments/Conclusion:

The additional field trial data for potatoes are adequate to satisfy the data requirement described in OPPTS 860.1500. Five potato field trials were conducted in regions I (1), V (1), IX (1), and XI (2) [i.e., CO (1), ID (1), MA (1), ND (1), and WA (1)]. All crops were treated two times with Select® 0.94 EC (also known as Prism) by ground spray application of 0.25 lb ai/A for a total application of 0.5 lb ai/A/season (1X) at 13 - 16 day intervals, and 31 days prior to harvest. The combined residues of DME and DME-OH ranged from <0.1 ppm (the LOD) to 0.70 ppm which support the proposed tolerance at 1.0 ppm for the Tuberous and Corm Vegetables Subgroup (1C Crop Subgroup 1-C).

cc: RF, PP# 7F4849, MXue, MRust  
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