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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OPP OFFICIAL RECORD  
HEALTH EFFECTS DIVISION  
SCIENTIFIC DATA REVIEWS  
EPA SERIES 361

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

9/20/2000

MEMORANDUM

**SUBJECT:** PP# 0E06097. Clethodim (ANSI) in/on Cucumbers and the Fruiting Vegetables (except Cucurbits) Crop Group. Evaluation of Analytical Method and Magnitude of the Residue Data.

DP Barcode: D268493  
Submission Nos: S574879

PRAT Case#: PC Code: 121011  
Caswell#: 721F  
EPA Reg#: 59639-78  
EPA Reg#: 59639-3  
40 CFR: §180.458

Trade Name: Select® Herbicide  
Select® 2EC Herbicide  
Class: Herbicide  
MRID Nos: 44753203, 44753204 and 44753205

**FROM:** Manying Xue, Chemist  
Registration Action Branch 3  
Health Effects Division (7509C)

*Manying Xue*

**THRU:** Stephen Dapson, Branch Senior Scientist  
Registration Action Branch 3  
Health Effects Division (7509C)

*Stephen C. Dapson*  
09/20/2000

**TO:** Joanne Miller, PM Team # 23  
Registration Division (7505C)

INTRODUCTION

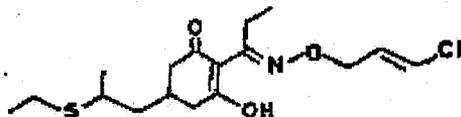
The IR-4 Project, Center for Minor Crop Pest Management, the Technology Centre of New Jersey, North Brunswick, NJ has submitted residue data for clethodim and its metabolites in/on cucumbers, bell peppers and non-bell peppers in support of their request for label amendments and permanent tolerances for residues of the herbicide clethodim (Select® Herbicide 0.94EC (also called Prism) and Select® 2EC Herbicide (EPA File Nos 59639-78 and 59639-3). The proposed tolerances for the combined residues of clethodim [(E)-(±)-2-[1-[[[3-chloro-2-propenyl)oxy]imino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one] and its metabolites containing the 5-(2-(ethylthiopropyl)cyclohexene-3-one and 5-(2-(ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulphoxides and sulphones are 0.50 ppm for cucumbers and 1.0 ppm for the Fruiting Vegetables (except Cucurbits) Crop Group.

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Clethodim is a member of the cyclohexenone class of herbicides. Tolerances for various plant and animal commodities for the combined residues of clethodim[(E)-(±)-2-[1-[[3-chloro-2-propenyl)oxy]imino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one] and its metabolites containing the 5-(2-(ethylthiopropyl)cyclohexene-3-one and 5-(2-(ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulfoxides and sulphones have been established (40 CFR §180.458). The established tolerances are at 1.0 ppm for cottonseed, 2.0 ppm for cottonseed meal, 0.2 ppm for livestock fat, livestock meat by-products, livestock meat, and poultry fat, meat and meat-by-products, 1.0 ppm for eggs, 0.5 ppm for potatoes, 1.0 ppm for potato flakes/granules, 0.05 ppm for milk, 10.0 ppm for soybeans, and 15.0 ppm for soybean soapstock, 0.2 ppm for dry bulb onions and sugar beet roots, 0.50 ppm for sugar beet tops, and 2.0 ppm for sugar beet molasses. Time-limited tolerances (expiration date 4/30/2001) are established at 6.0 ppm for alfalfa forage, 10 ppm for alfalfa hay, 2 ppm for dry beans, 3 ppm for peanuts and peanut hay, 5 ppm peanut meal, 1.0 ppm for tomatoes, 3 ppm for tomato paste, and 2 ppm for tomato puree.

This review was performed by the Oak Ridge National Laboratory, Oak Ridge, TN. The data assessment has undergone secondary review within RAB3 and has been revised to reflect current HED and OPP policies.

The chemical structure for clethodim is given below:



[(E)-(±)-2-[1-[[3-chloro-2-propenyl)oxy]imino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one]

## CONCLUSIONS

### OPPTS 830 Series GLNs: Product Properties

1. Product chemistry data for clethodim were previously submitted. The manufacturing process of the technical grade active ingredient (TGAI) and the formulations were reviewed (PP#9F3743, M. Nelson, 3/12/90). No deficiencies and no toxicological concerns for any clethodim impurities were cited.

### OPPTS GLN 860.1200: Proposed Uses

- 2a. The proposed use directions for cucumbers and peppers are inadequate. A revised Section B/label must be submitted which specifies a maximum of 2 applications at 0.25 lb ai/A for

a total of 0.5 lb ai /A/season for cucumbers and peppers. Preharvest intervals (PHIs) should remain at 14 days for cucumber and 20 days for peppers.

- 2b. There are errors on the labels of Select® 2 EC and Select® 0.94 EC. According to the field trial data, the petitioner needs to correct the statement on page 7 for Select® 2 EC label that reads "do not apply more than 32 fl oz of Select® 2 EC herbicide (0.08 lb. ai)". The statement should be "do not apply more than 32 fl oz of Select® 2 EC herbicide (0.5 lb. ai)". Similarly, on the Select® 0.94 EC label, the statement on page 7 should be "do not apply more than 68 fl oz of Select® 0.94 EC herbicide (0.5 lb. ai)", instead of "do not apply more than 68 fl oz of Select® 0.94 EC herbicide (0.08 lb. ai)".

OPPTS GLN 860.1300: Nature of the Residue - Plants

3. No new plant metabolism study has been submitted with this petition. Metabolism studies for clethodim in/on carrots, soybeans, and cotton were reviewed (PP#9F3743, MRIDs 41030137 & 41030138, M. Nelson 3/12/90). The qualitative nature of the clethodim residue in the fruiting vegetable (except Cucurbits) crop group is adequately understood for the purpose of this IR-4 petition. HED previously concluded that the residues of concern are clethodim and its metabolites containing the 2-cyclohexen-1-one moiety. However, the residues of concern are now described as metabolites containing the 5-(2-(ethylthiopropyl)cyclohexene-3-one and 5-(2-(ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulphoxides and sulphones in order to harmonize with the Codex MRL (PP#4F4340, D203378, J.Morales, 1/31/95).

OPPTS GLN 860.1300: Nature of the Residue - Animals

4. As livestock feed items are not associated with cucumbers and the Fruiting Vegetables (except cucurbits) crop group (OPPTS 860.1000), issues concerning the metabolism of clethodim in livestock are not germane for this petition.

OPPTS GLN 860.1340: Analytical Methods - Plants

- 5a. The method RM-26B-3 was validated for bell peppers at fortification levels of 0.1 ppm, 0.2 ppm, and 0.5 ppm. The limit of quantitation was determined to be 0.1 ppm for bell peppers. The recoveries for clethodim sulfoxide (CSO) ranged from 82-116% at fortification levels of 0.2 ppm and 0.5 ppm. The recoveries for 5-OH clethodim sulfone (5-OH CSO<sub>2</sub>) ranged from 74-145% at fortification levels of 0.1 ppm, 0.2 ppm, and 0.5 ppm. The common moiety method RM-26B-3 (a modification of RM-26B-2) for the determination of clethodim and its metabolites in plants is acceptable for data collection.
- 5b. The method RM-26B-3 was validated for non-bell peppers at fortification levels of 0.1 ppm, 0.2 ppm, and 0.5 ppm. The limit of quantitation was determined to be 0.2 ppm for non-bell peppers. The recoveries for clethodim sulfoxide (CSO) ranged from 90-101% at fortification levels of 0.2 ppm and 0.5 ppm. The recoveries for 5-OH clethodim sulfone (5-OH CSO<sub>2</sub>) ranged from 69-129% at fortification levels of 0.2 ppm, 0.5 ppm and 1.3 ppm. The common moiety method RM-26B-3 (a modification of RM-26B-2) for the

determination of clethodim and its metabolites in plants is acceptable for data collection.

- 5c. Method RM-26B-2 for the determination of clethodim and its metabolites in cucumbers is acceptable for data collection and enforcement purposes. The recoveries for clethodim sulfoxide (CSO) ranged from 86 - 118% at a fortification level of 0.12 ppm, and 89 - 104% at a fortification level of 1.12 ppm. The recoveries for 5-OH clethodim sulfone (5-OH CSO<sub>2</sub>) ranged from 87 - 112% at a fortification level of 0.1 ppm and 102 - 111% at a fortification level of 9.25 ppm. The limit of quantitation was determined to be 0.1 ppm.
- 5d. An adequate enforcement method is available for cucumbers and the Fruiting Vegetable (except Cucurbits) crop group. The common moiety method RM-26B-3 for the determination of clethodim and its metabolites is similar to the common moiety method RM-26B-2. The method RM-26B-2 has previously undergone a successful Petition Method Validation by the Agency (PP#9F3734, MRID 41388901, M. Nelson, 5/4/90), and a confirmatory method, EPA-RM-26D-2 is also available. Method (RM-26B-2) has been forwarded to FDA as an enforcement method for inclusion in PAM II.

OPPTS GLN 860.1340: Analytical Methods - Animals

6. Adequate analytical methodology is available to enforce tolerances for residues of clethodim and its metabolites in animal commodities. The Agency has concluded that the compound specific method, EPA-RM-26D-2, is suitable for enforcement of tolerances for the total clethodim residue in crops and animal tissues, and it has been forwarded to FDA for publication in PAM II.

OPPTS GLN 860.1360: Multiresidue Method

7. The petitioner has determined recoveries of clethodim, clethodim sulfoxide, and 5-OH clethodim sulfone using FDA's multiresidue protocols. Specific tests using the protocols were previously submitted and forwarded to FDA for review.

OPPTS GLN 860.1380: Storage Stability Data - Plants

8. The existing storage stability data are adequate to support the field trial data for cucumber, bell pepper and non-bell pepper. Residues of clethodim and its metabolites are stable under frozen storage for 526 days (approximately 17.5 months) in cucumbers and 713 days (approximately 24 months) in bell-peppers. No storage stability data were submitted for non-bell peppers. However, the 24 month storage stability data for bell peppers can be translated to non-bell peppers.

OPPTS GLN 860.1500: Crop Field Trials

- 9a. Provided that a revised Section B/label is submitted as specified in Conclusion 2a, the submitted field trial data and geographic representation for cucumbers are adequate to satisfy the data requirements described in OPPTS 860.1500. Six cucumber field trials were conducted in regions: I (1), II (1), III (1), V (2), and VI (1). Both pickling and slicing

varieties were used and were treated two times with Select® 0.94EC by ground spray application of 0.25 lb ai/A for a total of 0.5 lb ai/A/season (1X). The first application was about 30 days after emergence. Samples were harvested 14 days following the final application. The spray volume for the trials was between 19.4 and 34 GPA and included a tank-mixed crop oil concentrate at 1% v/v of the final spray. Total clethodim residues were measured as DME and DME-OH. All residues in cucumbers were less than the LOQ. The LOQ for DME was 0.12 ppm (converted to 0.14 ppm clethodim) and the LOQ for DME-OH was 0.11 ppm (converted to 0.13 ppm clethodim). The data support the proposed tolerance of 0.5 ppm in cucumber.

- 9b. **Provided that a revised Section B/label is submitted as specified in Conclusion 2a, the submitted field trial data and geographic representation for bell peppers are adequate to satisfy the data requirements described in OPPTS 860.1500.** Six bell pepper field trials were conducted in Regions I (1), II (2), III (1), VI (1), and X (1). All crops were treated two times with Select® 0.94 EC by ground spray application of 0.25 lb ai/A for a total of 0.5 lb ai/A/season (1X). The first application was about 90 days after emergence or 60 days after transplanting; the second application was 14 days later (18 for the Florida trial) and 20 days prior to harvest. The spray volume for the trials was between 30 and 75.6 GPA and included a tank-mixed crop oil concentrate at 1 qt/A or 1% v/v. Total clethodim residues were measured as DME and DME-OH. Clethodim residues in treated bell peppers ranged from 0.11 ppm to 0.89 ppm which supports the proposed tolerance of 1.0 ppm for residues of clethodim and its metabolites in/on the fruiting vegetables (except cucurbits) crop group.
- 9c. **Provided that a revised Section B/label is submitted as specified in Conclusion 2a, the submitted field trial data and geographic representation for non-bell pepper are adequate to satisfy the data requirements described in OPPTS 860.1500.** Five non-bell pepper field trials were conducted in Regions I (1), II (1), III (1), VI (1), and X (1). All crops were treated with two applications of Select® 0.94 EC by ground spray at 0.25 lb ai/A for a total of 0.5 lb ai/A/season (1X). The first application was about 90 days after emergence or 60 days after transplanting. The second application was 14 days later and 20 days prior to harvest. The spray volume for the trials was between 30 and 75.6 GPA and included a tank-mixed crop oil concentrate at 1 qt/A or 1% v/v of the final spray. Clethodim residues were measured as DME and DME-OH. Residues in/on non-bell peppers ranged from 0.12 ppm to 0.92 ppm which supports the proposed tolerance of 1.0 ppm for residues of clethodim and its metabolites in/on the fruiting vegetables (except cucurbits) crop group.
- 9d. The petitioner has submitted field trial data for bell peppers, non-bell peppers, and tomatoes to support a tolerance on the Fruiting Vegetables (except Cucurbits) crop group. The field trial data for bell peppers and non-bell peppers are adequate. However, the residue data for tomatoes are not adequate (PP#5F4572/5H5729, D219077, J. Morales, 12/11/95); four additional field trials in California were required. The deficiency has not been resolved. **HED still requires the four additional tomato field trial studies for establishment of a permanent tolerance on the Fruiting Vegetables (except Cucurbits) crop group.** Therefore, a conditional registration for the Fruiting Vegetables (except Cucurbits) crop group is recommended.

OPPTS GLN 860.1520: Processed Food/Feed

- 10a. Time-limited tolerances for residues of clethodim and its metabolites in/on tomato paste at 3.0 ppm and tomato puree at 2 ppm have been established. The permanent tolerance for residues of clethodim and its metabolites in/on tomato paste and puree will be established when the additional tomato field trial data are submitted.
- 10b. There are no regulated processed foods or feeds derived from the commodities associated with cucumbers, bell peppers and non-bell peppers.

OPPTS GLN 860.1480: Magnitude of the Residue in Meat/Milk/Poultry/Eggs

11. No feeding studies have been submitted with this petition. As livestock feeds are not derived from cucumbers and the Fruiting Vegetables (except Cucurbits) crop group, secondary residues in/on livestock commodities are not expected to occur in/on livestock commodities. This use falls under 40 CFR 180.6(a)(3).

OPPTS GLN 860.1850 and 860.1900: Confined/Field Accumulation in Rotational Crops

12. A confined rotational crop study for [ring-4,6-<sup>14</sup>C]-clethodim with carrots, lettuce, and wheat (MRID 41030211) was conducted. The study was reviewed by E. B. Conerly (EFGWB Science Chapter for Clethodim, 06/26/1990). A 1-month plantback interval for crops rotated with alfalfa was specified (D 236382, M. Collantes, et. al, 2/10/98). The use directions submitted with the current petition do not specifically address rotational crops. The directions for use on fallow or nonproducing agricultural land is to not plant any crop for 30 days after application unless clethodim is registered for use on that crop. **A revised Section B/label must be submitted which includes a 1-month plantback restriction for all rotated crops without clethodim registered uses.**

International Harmonization of Tolerances

13. Codex, Canadian, or Mexican maximum residue levels (MRLs) have been established or proposed for residues of clethodim in/on fodder beet (0.1 ppm), sugar beet (0.1 ppm), potato (0.2 ppm), rape seed (0.5 ppm), rape seed oils (0.5 ppm), sunflower seed (0.5 ppm), and sunflower seed oils (0.05 ppm). Some of these proposed tolerances have been recommended for withdrawal or have been recently changed. Harmonization could be an issue for Codex MRLs for potato/tuberous vegetables (0.2 ppm vs. 1.0 U.S.), sunflower seed (0.5 ppm vs. 5.0 ppm) and sunflower oils (0.05 ppm vs. 5.0 ppm U.S.). There could be a harmonization issue with the Canadian MRLs for potatoes (0.5 ppm vs. 1.0 ppm U.S.), sunflowers (0.2 ppm vs. 5.0 ppm U.S.), and rape/canola (0.05 ppm vs. 0.5 ppm U.S.). There are also current Codex harmonization concerns for clethodim residues in chicken meat, eggs, milk, sugar beets (roots), cottonseed, cottonseed oil, and dry bulb onions.

RECOMMENDATIONS

Provided a revised Section B/label is submitted as specified in Conclusion 2a, HED concludes that there are no residue chemistry data requirements that would preclude the establishment of permanent

tolerances for residues of clethodim and its metabolites in/on cucumbers.

Pending submission of four additional tomato field trials (Conclusion 9d), registration of the Fruiting Vegetables (except Cucurbits) crop group should be made conditional. HED recommends that the time-limited tolerance for tomatoes should be removed from CFR 180.458.

HED recommends that the tolerance levels for the combined residues of clethodim [(E)-(±)-2-[1-[[[(3-chloro-2-propenyl)oxy]imino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one] and its metabolites containing the 5-(2-(ethylthiopropyl)cyclohexene-3-one and 5-(2-(ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulfoxides and sulphones should be established as follows:

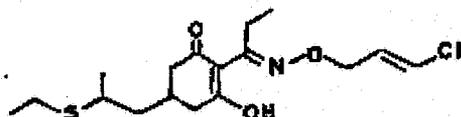
Cucumbers	0.50 ppm
Fruiting Vegetables (except Cucurbits)	1.0 ppm

Upon submissions of the required data, these tolerances may be reevaluated. HED will now initiate a Human Health Risk Assessment for these uses.

### DETAILED CONSIDERATIONS

#### OPPTS 830 Series GLNs: Product Properties

The chemical structure for clethodim is given below:



[(E)-(±)-2-[1-[[[(3-chloro-2-propenyl)oxy]imino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one]

Select® 0.94EC and Select® 2EC Herbicides contain 12.6% and 26.4 %, respectively, of the active ingredient clethodim (0.94 lb ai/gal or 2.0 lb ai/gal). The product chemistry data for clethodim were previously submitted. The manufacturing process for the technical grade active ingredient (TGAI) and the formulations were reviewed ( PP#9F3743, M. Nelson, 3/12/90). No deficiencies and no toxicological concerns for any clethodim impurities were cited.

## **OPPTS GLN 860.1200: Proposed Uses**

### **Formulations:**

Two registered formulations of clethodim are proposed for use: (1) Select® 2 EC Herbicide (EPA Reg. No. 59639-3) is an emulsifiable concentrate containing 26.4% of active ingredient (ai) and 75% of inerts. This formulation contains 2 pounds of ai per gallon.

(2) Select® 0.94EC (EPA Reg. No. 59639-78) is an emulsifiable concentrate containing 12.6% of active ingredient (ai) and 87.4% of inerts. The formulation contains 0.94 pounds of ai per gallon.

### **Cucumbers**

Apply Select® 0.94EC at a rate up to 0.125 lb ai/A (17 fl oz/A) with no more than 0.5 lb ai/A/season (68 fl oz/A/season). Apply Select® 2EC at a rate of 0.125 lb ai/A (8 fl. oz/A) with no more than 0.5 lb ai/A/season (32 fl oz/A/season). The proposed PHI is 14 days for cucumbers.

### **Peppers, Bell and Non-Bell**

Apply Select® 0.94EC at a dose rate up to 0.125 lb ai/A (17 fl oz/A) per application/treatment with no more than 0.5 lb ai/A/season (68 fl oz/A/season). Apply Select® 2EC at a dose rate of 0.125 lb ai/A (8 fl. oz/A) per application/treatment with no more than 0.5 lb ai/A/season (32 fl oz/A/season). The proposed PHI is 20 days for peppers.

### **HED Comments/Conclusions:**

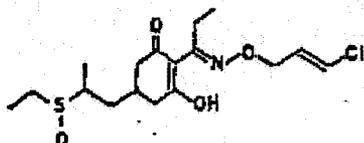
The proposed use directions for cucumbers and peppers are inadequate. A revised Section B/label must be submitted which specifies a maximum of 2 applications at 0.25 lb ai/A for a total of 0.5 lb ai /A/season for cucumbers and peppers. Preharvest intervals (PHIs) should remain at 14 days for cucumber and 20 days for peppers.

There are errors on the labels of Select® 2 EC and Select® 0.94 EC. The petitioner needs to correct the statement on page 7 for Select® 2 EC label that reads "do not apply more than 32 fl oz of Select® 2 EC herbicide (0.08 lb. ai.)". The statement should be "do not apply more than 32 fl oz of Select® 2 EC herbicide (0.5 lb. ai.)". Similarly, on the Select® 0.94 EC label, the statement on page 7 should be "do not apply more than 68 fl oz of Select® 0.94 EC herbicide (0.5 lb. ai.)", instead of "do not apply more than 68 fl oz of Select® 0.94 EC herbicide (0.08 lb. ai.)".

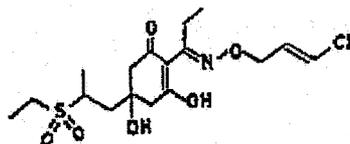
## **OPPTS GLN 860.1300: Nature of the Residue - Plants**

No new plant metabolism study has been submitted with this petition. Metabolism studies for clethodim in/on carrots, soybeans, and cotton was submitted with PP#9F3743 (MRIDs 41030137 & 41030138) and discussed in M. Nelson's memo of 3/12/90. Immature carrots, soybeans, and cotton were treated twice at a 14-day interval with a 50:50 tautomeric mixture of ring [6-<sup>14</sup>C]-clethodim at a rate equivalent to 0.25 lbs. ai/A as a postemergence foliar spray; grown to maturity in a greenhouse; and harvested with PHIs of 20, 30, and 70 days. The major metabolic pathways of

clethodim (C) in plants are initial sulfoxidation to clethodim sulfoxide (CSO, structure shown below) followed by further oxidation to clethodim sulfone (CSO<sub>2</sub>), elimination of the chloroallyloxy side chain to give the imine sulfoxide (ISO) and sulfone (ISO<sub>2</sub>), and hydroxylation to form the 5-OH sulfoxide (5OH-SO) and sulfone (5OH-SO<sub>2</sub>, structure shown below). Clethodim sulfoxide and clethodim sulfone conjugates were also detected as major or minor metabolites, depending on plant species and subfractions. Data are shown in Table 1. Also present as a minor metabolite was the aromatic sulfone. A study designed to follow the fate of the chloroallyloxy group was done side-by-side with the <sup>14</sup>C-ring-labeled clethodim study discussed above. The results showed that the chloroallyloxy moiety cleaved from clethodim underwent extensive metabolism, eliminating the chlorine atom and incorporating the three carbon moieties into natural plant components (with some being evolved as <sup>14</sup>CO<sub>2</sub>). Studies have been conducted only in a root crop (carrots) and two oilseeds (soybean and cotton) and it cannot be stated that the nature of the residue is understood in all plants. The residue of concern is clethodim and its metabolites containing the 2-cyclohexen-1-one moiety which are now described as metabolites containing the 5-(2-(ethylthiopropyl)cyclohexene-3-on) and 5-(2-(ethylthiopropyl)-5-hydroxycyclohexene-3-on) moieties and their sulfoxides and sulphones.



Clethodim sulfoxide



5-Hydroxy clethodim sulfone

Table. 1. Characterization of Clethodim Metabolites in Plant Tissues						
Component	ppm (calculated as clethodim from <sup>14</sup> C -labeled clethodim)					
	Soybean Bean	Soybean Foliage	Cotton seed	Cotton Foliage	Carrot Root	Carrot Leaves
C	---	---	---	---	0.003	---
CSO	1.24	1.65	0.003	0.55	0.11	3.50
CSO <sub>2</sub>	0.178	0.25	0.002	0.054	0.014	0.13
ISO	0.302	3.88	0.004	2.40	0.040	4.93
ISO <sub>2</sub>	0.314	2.43	0.002	0.55	0.034	1.32
5OH-SO	0.275	<0.05	<0.001	0.19	0.026	0.36
5OH-SO <sub>2</sub>	0.414	0.86	0.001	0.054	0.030	0.42
Arom. SO <sub>2</sub>	0.58	0.14	<0.001	0.068	0.006	0.067
Others	0.271 <sup>a</sup>	3.63 <sup>a</sup>	0.0045 <sup>b</sup>	4.22 <sup>a</sup>	0.052 <sup>a</sup>	2.419 <sup>a</sup>
CSO-Conj.	0.329	6.92	<0.001	0.37	0.024	1.90
CSO <sub>2</sub> -Conj.	0.050	0.56	<0.001	0.18	0.002	0.11
Other Conj.	0.383 <sup>a</sup>	5.11 <sup>a</sup>	0.020 <sup>c</sup>	4.25 <sup>a</sup>	0.041 <sup>b</sup>	5.98 <sup>a</sup>
Non-extractable	0.058	2.48	0.032	0.62	0.015	1.18
Totals	3.872	27.94	0.069	13.51	0.397	22.32

Data from D. Dotson, Memo, D2124704 (12/19/97)

<sup>a</sup> Composed of  $\geq 9$  <sup>14</sup>C metabolites

<sup>b</sup> Composed of  $\geq 4$  <sup>14</sup>C metabolites

<sup>c</sup> Contained too low radioactivity to allow further characterization.

Abbreviations are referenced in the previous text.

**HED Comments/Conclusions:**

No new plant metabolism study has been submitted with this petition. Metabolism studies for clethodim in/on carrots, soybeans, and cotton were reviewed (PP#9F3743, MRIDs 41030137 & 41030138, M. Nelson 3/12/90). The qualitative nature of the clethodim residue in the fruiting vegetable (except Cucurbits) crop group is adequately understood for the purpose of this IR-4 petition. HED previously concluded that the residues of concern are clethodim and its metabolites containing the 2-cyclohexen-1-onemoiety. However, the residues of concern are now described as metabolites containing the 5-(2-(ethylthiopropyl)cyclohexene-3-one and 5-(2-(ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulphoxides and sulphones in order to harmonize with the Codex MRL (PP#4F4340, D203378, J.Morales, 1/31/95).

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**OPPTS GLN 860.1300: Nature of the Residue - Livestock**

As livestock feed items are not associated with cucumbers and the Fruiting Vegetables (except cucurbits) crop group (OPPTS 860.1000), issues concerning the metabolism of clethodim in livestock are not germane for this petition.

**OPPTS GLN 860.1340: Analytical Methods - Plants**

**Method RM-26B-3**

Method RM-26B-3 (a modification of RM-26B-2) was used for the analyses of bell peppers and non-bell peppers. The analyses were conducted at 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 which are cleft 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. This method is a modification of RM-26B-2 and updates measurement parameters, calculation procedures and modifies the silica gel cleanup procedure. The fortification levels and recovery data are reported in Table 3 and Table 4.

**Bell Peppers**

Table 3. Method recovery of clethodim (CS), clethodim sulfoxide (CSO), and 5-OH clethodim sulfone (5-OH CSO <sub>2</sub> ) from fortified bell pepper samples.							
Matrix	Fortification Level (ppm)	(number of analyses) Range of Recoveries					
		CS (ppm) <sup>a</sup>	CS (%) <sup>b</sup>	CSO (ppm) <sup>a</sup>	CSO (%) <sup>b</sup>	5-OH CSO <sub>2</sub> (ppm) <sup>a</sup>	5-OH CSO <sub>2</sub> (%) <sup>b</sup>
Bell pepper	0.1	(2)0.12-0.13	117-131	0	-	(2)0.14-0.15	138-145
	0.107	(2)0.13-0.16	94-116	0	-	0	-
	0.133	-	-	0	-	(2)0.16-0.17	116-124
	0.2	(3)0.20-0.26	76-107	(3)0.20-0.26	99-116	(6)0.16-0.22	78-109
	0.5	(3)0.47-0.50	81-94	(2)0.41-0.5	82-99	(5)0.37-0.46	74-92
Average (%) ± SD <sup>c</sup>		NC	100 ± 18	NC	99 ± 14	NC	101 ± 21

<sup>a</sup>Uncorrected for untreated control

<sup>b</sup>Corrected for untreated control

<sup>c</sup>Averages calculated by the reviewer from original unrounded data. Average not calculated (NC) for ppm values.

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Non-bell Peppers

Table 4. Method recovery of clethodim(CS) or clethodim sulfoxide (CSO) as DME, and 5-OH clethodim sulfone (5-OH CSO <sub>2</sub> ) as DME-OH from fortified non- bell pepper samples.							
Matrix	Fortification Level (ppm)	(number of analyses) Range of Recoveries					
		CS (ppm) <sup>a</sup>	CS (%) <sup>b</sup>	CSO (ppm) <sup>a</sup>	CSO (%) <sup>b</sup>	5-OH CSO <sub>2</sub> (ppm) <sup>a</sup>	5-OH CSO <sub>2</sub> (%) <sup>b</sup>
Non-bell pepper	0.2	(0)	-	(2) 0.19-0.25	92-97	(2) 0.18-0.26	89-129
	0.214	(2) 0.22-0.23	83-102	(0)	-	0	-
	0.266	(0)	-	(0)	-	(2) 0.21-0.23	79-85
	0.5	(1) 0.58	105	(2) 0.51-0.51	90-101	(3) 0.43-0.53	72-107
	0.535	(1) 0.47	88	(0)	-	(0)	-
	0.665	(0)	-	(0)	-	(1) 0.53	80
	1.07	(1) 0.74	69.4	(0)	-	(0)	-
	1.33	(0)	-	(0)	-	(1) 0.92	69
Average (%) ± SD <sup>c</sup>		NC	90 ± 14	NC	95 ± 5	NC	89 ± 19

<sup>a</sup>Uncorrected for untreated control

<sup>b</sup>Corrected for untreated control

<sup>c</sup>Averages calculated by the reviewer from original unrounded data. Average not calculated (NC) for ppm values.

Method RM-26B-2

Method RM-26B-2 was used for the analysis of cucumbers by the Pesticide Research Center, Michigan State University, East Lansing, MI. The method RM-26B-2 has successfully undergone an EPA method validation (PP#9F3734, MRID 41388901, M. Nelson, 5/4/90). Samples were fortified with CSO and 5-OH CSO<sub>2</sub>. The results were reported as DME and DME-OH, respectively, and converted to clethodim equivalents. The method involves extraction with aqueous methanol, cleanup by alkaline precipitation and acidic back extraction, oxidation to the pentanedioic acid moieties, derivatization to the corresponding dimethyl esters (DME and/or DME-OH), partition of the dimethyl esters in CH<sub>2</sub>Cl<sub>2</sub>, and determination by GC-FPD-S. The total residue is expressed as clethodim equivalents. The limit of quantitation is 0.10 ppm. The results are in Table 5.

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**Table 5. Method recovery of clethodim sulfoxide (CSO) and 5-OH clethodim sulfone (5-OH CSO<sub>2</sub>) as DME and DME-OH, respectively, from fortified cucumber samples.**

Matrix	Fortification Level (ppm)				
		CSO (ppm) Found	CSO (%)	5-OH CSO <sub>2</sub> (ppm) Found	5-OH CSO <sub>2</sub> (%)
Cucumbers	0.12	0.12, 0.11, 0.12, 0.14, 0.14, 0.14, 0.14, 0.11, 0.10, 0.11, 0.14, 0.10, 0.10, 0.12, 0.12, 0.12	86 - 118		
	0.93 - 0.11			0.10, 0.10, 0.09, 0.10, 0.11, 0.11, 0.09, 0.11, 0.12, 0.09, 0.10, 0.10, 0.10, 0.11, 0.10, 0.10	87 - 112
	1.12	1.03, 1.20	89 - 104		
	9.25			0.95, 1.03	102 - 111

\*Averages calculated by the reviewer from original unrounded data. Average not calculated (NC) for ppm values.

**HED Comments/Conclusions:**

The method RM-26B-3 was validated for bell peppers at fortification levels of 0.1 ppm, 0.2 ppm, and 0.5 ppm. The limit of quantitation was determined to be 0.1 ppm for bell peppers. The recoveries for clethodim sulfoxide (CSO) ranged from 82-116% at fortification levels of 0.2 ppm and 0.5 ppm. The recoveries for 5-OH clethodim sulfone (5-OH CSO<sub>2</sub>) ranged from 74-145% at fortification levels of 0.1 ppm, 0.2 ppm, and 0.5 ppm. The common moiety method RM-26B-3 (a modification of RM-26B-2) for the determination of clethodim and its metabolites in plants is acceptable for data collection.

The method RM-26B-3 was validated for non-bell peppers at fortification levels of 0.1 ppm, 0.2 ppm, and 0.5 ppm. The limit of quantitation was determined to be 0.2 ppm for non-bell peppers. The recoveries for clethodim sulfoxide (CSO) ranged from 90-101% at fortification levels of 0.2 ppm and 0.5 ppm. The recoveries for 5-OH clethodim sulfone (5-OH CSO<sub>2</sub>) ranged from 69-129% at fortification levels of 0.2 ppm, 0.5 ppm and 1.3 ppm. The common moiety method RM-26B-3 (a modification of RM-26B-2) for the determination of clethodim and its metabolites in plants is acceptable for data collection.

Method RM-26B-2 for the determination of clethodim and its metabolites in cucumbers is acceptable for data collection and enforcement purposes. The recoveries for clethodim sulfoxide (CSO) ranged from 86 - 118% at a fortification level of 0.12 ppm, and 89 - 104% at a fortification level of 1.12 ppm. The recoveries for 5-OH clethodim sulfone (5-OH CSO<sub>2</sub>) ranged from 87 - 112% at fortification level of 0.1 ppm and 102 - 111% at a fortification level of 9.25 ppm. The limit of quantitation was determined to be 0.1 ppm.

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An adequate enforcement method is available for cucumbers and the Fruiting Vegetable (except Cucurbits) crop group. The common moiety method RM-26B-3 for the determination of clethodim and its metabolites is similar to the common moiety method RM-26B-2. The method RM-26B-2 has previously undergone a successful Petition Method Validation by the Agency (PP#9F3734, MRID 41388901, M. Nelson, 5/4/90), and a confirmatory method, EPA-RM-26D-2 is also available. Method (RM-26B-2) has been forwarded to FDA as an enforcement method for inclusion in PAM II.

**OPPTS GLN 860.1360: Multiresidue Method**

The petitioner has determined recoveries of clethodim, clethodim sulfoxide, and 5-OH clethodim sulfone under FDA's multiresidue protocols. Specific tests using the protocols were previously submitted and forwarded to FDA for review.

**OPPTS GLN 860.1380: Storage Stability Data -Plants**

**Cucumber**

Storage stability data are adequate to support magnitude of residue studies in/on cucumbers. The storage stability of clethodim and its metabolites in/on cucumbers was studied concurrently with the field trials. Aliquots of cucumber were fortified with 1.4 ppm clethodim sulfoxide and 1.3 ppm 5-hydroxy clethodim sulfone. The fortified samples were extracted and analyzed after 518 and 526 days of frozen storage. The recoveries were comparable to the method validation recoveries. The results of the storage stability test in cucumbers is given in Table 6. The field trial samples were stored for up to 458 days (15 months) prior to extraction.

Table 6. Recoveries of clethodim and its metabolites from cucumber after frozen storage		
Chemical Fortified (ppm added)	Average % for Sample Stored 518 Days	Average % for Sample Stored 526 Days
Clethodim Sulfoxide (1.410 )	83	91
5-OH Clethodim Sulfone (1.267)	95	97

Data from MRID447532-03, pg 19.

**Bell Peppers**

Storage stability data for clethodim and its metabolites in/on bell peppers has been submitted with this petition (MRID 44753204). Storage samples were analyzed after 645 and 713 days of frozen storage. The results of the storage stability test in bell peppers are given in Table 7. The maximum storage interval for the field trials was 24 months.

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Chemical Fortified (ppm added)	Average %	Fresh Recovery %	Days stored	Average %	Fresh Recovery %	Days Stored
Clethodim (0.1 )	124	94-116	645	119	131	713
5-OH Clethodim Sulfone (0.1)	127	116-124	645	163	145	713

Data from MRID447532-04, pp 22-23, 110, 117.

### Pepper (Non-Bell)

The field samples of non-bell peppers were stored for up to 726 days (ca. 24 months). No storage stability data were submitted with this petition. However, the 24 month storage stability data for bell peppers can be translated to non-bell peppers. Therefore, no storage stability data for non-bell peppers are required.

### HED Comments and Conclusions:

The existing storage stability data are adequate to support the field trial data for cucumber, bell pepper and non-bell pepper. Residues of clethodim and its metabolites are stable under frozen storage for 526 days (approximately 17.5 months) in cucumbers and 713 days (approximately 24 months) in bell-peppers. No storage stability data were submitted for non-bell peppers. However, the 24 month storage stability data for bell peppers can be translated to non-bell peppers.

### OPPTS GLN 860.1500: Crop Field Trials

#### Cucumber

Six cucumber field trials were conducted in New York (1), South Carolina (1), Florida (1), Michigan (1), Wisconsin (1), and Texas (1). The field trial results are reported in :

MRID 447532-03. Lai, J.C. and D. L. Kunkel (1998) Clethodim: Magnitude of the Residues on Cucumbers. IR-4 Project, Center for Minor Crop Pest Management, 681 U.S. Highway #1, South, North Brunswick, NJ 08902-3390 and Valent U.S.A. Corporation, 1333 North California Blvd., Suite 600, P.O. Box 8025, Walnut Creek, CA, 94596-8025. Performing Laboratory: IR-4 Project, Center for Minor Crop Pest Management, 681 U.S. Highway #1, South, North Brunswick, NJ 08902-3390 and Pesticide Research Center, Michigan State University, East Lansing, MI 48824-1311. Laboratory ID: 05219, December 18, 1998. 1 Volume, Unpublished.

Cucumber trials were conducted in 1994 and 1995 (SC and TX only) and a total of 5 different varieties of cucumber were used. All were treated two times with Select® 0.94EC (also known as Prism) by ground spray application of 0.25 lb ai/A for a total of 0.5 lb ai/A/season (1X ). The first application was about 30 days after emergence. The second application was 14 days later and 14 days prior to harvest. The spray volume for the trials was between 19.4 and 34 GPA and included

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a tank-mixed crop oil concentrate at 1% v/v of the final spray. At least 12 slicer cucumbers were sampled by hand from randomly located plants across the plot for a total sample consisting of at least 4 pounds. Pickling cucumber samples consisted of 4 pounds of fruit. The loose dirt was brushed off with a soft cloth or brush. The samples (except those from the Michigan trial) were frozen promptly and sent to the Pesticide Research Center, Michigan State University, East Lansing, MI for analysis. The Michigan trial samples were received fresh at the laboratory within 80 minutes of harvest and were frozen at the laboratory. Whole cucumbers were macerated in a Hobart food chopper prior to analysis.

Cucumber samples were analyzed for residues of clethodim and its metabolites using method RM-26B-2 at the limit of quantitation of 0.14 ppm for DME and at 0.13 ppm for DME-OH. All residues in cucumbers were less than the LOQ for both DME (0.12 ppm, converted to 0.14 ppm clethodim) and DME-OH (0.11 ppm, converted to 0.13 ppm clethodim). The total residues were less than the LOQ and support the proposed tolerance of 0.5 ppm for residue of clethodim and its metabolites in/on cucumber. Table 8 contains a summary of the residues in/on cucumber. The Michigan trials also had Poast® (sethoxydim) applied to the plots used in the study but this did not prove to be an issue as there were no quantifiable residues of either common metabolite for these herbicides.

Test ID	State	PHI days	lb ai/A per application (includes crop oil concentrate at 1%)	ppm Found as Clethodim		
				DME	DME-OH	Total
94-NY10	NY	14	0.25	<0.14 (0.03, 0.03) <sup>a</sup>	<0.13 (ND, ND) <sup>b</sup>	<0.27 <sup>c</sup>
94-SC*08	SC	13	0.30-0.31	<0.14 (0.01, 0.03)	<0.13 (ND, ND)	<0.27
94-FL47	FL	14	.262	<0.14 (0.03, 0.03)	<0.13 (ND, ND)	<0.27
94-MI15	MI	13	0.255	<0.14 (0.07, 0.05)	<0.13 (ND, ND)	<0.27
94-WI13	WI	14	0.252-0.261	<0.14 (0.03, 0.04)	<0.13 (ND, ND)	<0.27
95-TX*45	TX	14	0.25	<0.14 (0.03, 0.06)	<0.13 (ND, ND)	<0.27

<sup>a</sup> Estimated values greater than detection limit but less than the LOQ level of reliability are given in parentheses.

<sup>b</sup> ND means the compound had no detectable signal on the chromatograph.

<sup>c</sup> The authors chose to represent the total as the sum of the detection limits. In reality, any measurable quantity above the LOD would be reported as the total, even if only detected as one metabolite.

**HED Comments/Conclusion:**

Provided that a revised Section B/label is submitted as specified in Conclusion 2a, the submitted field trial data and geographic representation for cucumbers are adequate to satisfy the data requirements described in OPPTS 860.1500. Six cucumber field trials were conducted in regions: I (1), II (1), III (1), V (2), and VI (1). Both pickling and slicing varieties were used and were treated two times with Select® 0.94EC by ground spray application of 0.25 lb ai/A for a total of 0.5 lb ai/A/season (1X). The first application was about 30 days after emergence. Samples were harvested

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14 days following the final application. The spray volume for the trials was between 19.4 and 34 GPA and included a tank-mixed crop oil concentrate at 1% v/v of the final spray. Total clethodim residues were measured as DME and DME-OH. All residues in cucumbers were less than the LOQ. The LOQ for DME was 0.12 ppm ( converted to 0.14 ppm clethodim) and the LOQ for DME-OH was 0.11 ppm (converted to 0.13 ppm clethodim). The data support the proposed tolerance of 0.5 ppm in cucumber.

### Bell Pepper

Six field trials for bell pepper were conducted in Regions I (1), II (2), III (1), VI (1), and X (1) [i.e. New York (1), North Carolina (1), Georgia (1), Florida (1), Texas (1) and California (1)]. The field trials results are reported in :

MRID 447532-04. Lai, J.C., D. L. Kunkel, and K.S. Samoil (1998) Clethodim: Magnitude of the Residues on Bell Pepper. IR-4 Project, Center for Minor Crop Pest Management, 681 U.S. Highway #1, South, North Brunswick, NJ 08902-3390 and Valent U.S.A. Corporation, 1333 North California Blvd., Suite 600, P.O. Box 8025, Walnut Creek, CA, 94596-8025. Performing Analytical Laboratory: Valent Technical Center, Valent U.S.A. Corporation, Dublin, CA 94568, Laboratory ID: 5226, December 18, 1998. 2 Volumes, Unpublished.

Trials were conducted in 1993 and 1994 (CA only) and a total of six different varieties of bell peppers were used. All crops were treated two times with Select® 0.94EC (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 as the 1X rate. The first application was about 90 days after emergence or 60 days after transplanting. The second application was 14 days later (18 days for the Florida trial) and 20 days prior to harvest. The spray volume for the trials was between 30 and 75.6 GPA and included a tank-mixed crop oil concentrate at 1 qt/A for the 1993 trials or 1% v/v of the final spray for 1994 trial. The bell peppers were frozen within 4 hours of harvest. Whole bell peppers were macerated prior to analysis. The samples were analyzed at Valent Technical Center, Dublin, CA using Method RM-26B-3.

Total clethodim residues were determined as DME and DME-OH. The total residue concentration in treated bell peppers ranged from 0.11 ppm to 0.89 ppm and supports the proposed tolerance of 1.0 ppm in fruiting vegetables (except cucurbits) crop group. Because of the limitations in the number of field trials only a crop group tolerance is supported. Concurrent recovery studies from fortified controls validated the methods. Table 9 contains a summary of the residues in/on bell peppers.

Table 9. Residues of clethodim and its metabolites in/on bell peppers treated twice with Select 0.94EC at 0.25 lb ai/A.						
Test ID	State	PHI (days)	lb ai/A per application (includes crop oil concentrate at 1% or 1 qt/A)	ppm Found as Clethodim		
				DME	DME-OH	Total
93-GA*02	GA	20	0.242-0.25	0.11, 0.14	NF <sup>a</sup> , <0.1 <sup>b</sup>	0.11, 0.14
93-TX*02	TX	21	0.255	0.17, 0.20	0.12, 0.14	0.29, 0.34
94-CA*96	CA	20	0.247-0.250	0.49, 0.43	0.13, 0.15	0.62, 0.58
93-FL17	FL	21	0.255	0.36, 0.34	0.18, 0.17	0.54, 0.51
93-NC01	NC	19	0.244-0.250	0.32, 0.27	0.13, 0.11	0.45, 0.38
93-NY01	NY	19	0.252	0.60, 0.46	0.29, 0.22	0.89, 0.68

<sup>a</sup> NF means that no residues were found, no signal on the chromatograph.

<sup>b</sup> <0.1 is less than the LOD of 0.1 ppm.

**HED Comments/Conclusion:**

Provided that a revised Section B/label is submitted as specified in Conclusion 2a, the submitted field trial data and geographic representation for bell peppers are adequate to satisfy the data requirements described in OPPTS 860.1500. Six bell pepper field trials were conducted in Regions I (1), II (2), III (1), VI (1), and X (1). All crops were treated two times with Select® 0.94 EC by ground spray application of 0.25 lb ai/A for a total of 0.5 lb ai/A/season (1X). The first application was about 90 days after emergence or 60 days after transplanting; the second application was 14 days later (18 for the Florida trial) and 20 days prior to harvest. The spray volume for the trials was between 30 and 75.6 GPA and included a tank-mixed crop oil concentrate at 1 qt/A or 1% v/v. Total clethodim residues were measured as DME and DME-OH. Clethodim residues in treated bell peppers ranged from 0.11 ppm to 0.89 ppm which supports the proposed tolerance of 1.0 ppm for residues of clethodim and its metabolites in/on the fruiting vegetables (except cucurbits) crop group.

**Non-Bell Pepper**

Five field trials for non-bell pepper were conducted in Regions I (1), II (1), III (1), VI (1), and X (1) [i.e. New Jersey (1), Georgia (1), Florida (1), Texas (1), and California (1)]. The field trials results are reported in :

MRID 447532-05. Lai, J.C., D. L. Kunkel, and K.S. Samoil (1998) Clethodim: Magnitude of the Residues on Pepper (Non-Bell). IR-4 Project, Center for Minor Crop Pest Management, 681 U.S. Highway #1, South, North Brunswick, NJ 08902-3390 and Valent U.S.A. Corporation, 1333 North California Blvd., Suite 600, P.O. Box 8025, Walnut Creek, CA, 94596-8025. Performing Analytical Laboratory: Valent Technical Center, Valent U.S.A. Corporation, Dublin, CA 94568, Laboratory ID: 5226, December 18, 1998. 2 Volumes, Unpublished.

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Trials were conducted in 1993 and 1994 (CA only) and a total of five different varieties of non-bell peppers were used. The Georgia trial used two varieties and both were sampled. 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). The first application was about 90 days after emergence or 60 days after transplanting; the second application was 14 days later and 20 days prior to harvest. The spray volume for the trials was between 30 and 75.6 GPA and included a tank-mixed crop oil concentrate at 1 qt/A for the 1993 trials or 1% v/v of the final spray for the 1994 trial. For the larger pepper varieties at least 16 peppers were sampled by hand from at least 8 randomly located plants across the plot for a total of 4 pounds, and for the smaller varieties at least 0.5 lb/A was sampled. The peppers were frozen within 4 hours of harvest. Whole peppers were macerated prior to analysis. The samples were analyzed at Valent Technical Center, Dublin, CA and Method RM-26B-3 was used.

Clethodim residues were reported in terms of residues of DME and DME-OH. The total residue concentration in treated non-bell peppers ranged from 0.12 ppm to 0.92 ppm. Table 10 contains a summary of the residues in/on non-bell peppers.

Table 10. Residues of clethodim and its metabolites in/on non-bell peppers treated twice with Select 0.94EC at 0.25 lb ai/A.						
Test ID	State	PHI days	lb ai/A per application (includes crop oil concentrate at 1% or 1 qt/A)	ppm Found as Clethodim		
				DME	DME-OH	Total
G	GA	20	0.243	0.12, 0.12	NF <sup>a</sup> , <0.1 <sup>b</sup>	0.12, 0.12
H	TX	21	0.255	0.22, 0.21	0.18, 0.18	0.40, 0.39
I	CA	20	.247-.250	0.62, 0.56	0.29, 0.26	0.91, 0.82
J	FL	21	0.255	0.25, 0.28	0.18, 0.20	0.43, 0.48
K	NJ	22	0.245-0.246	0.60, 0.59	0.32, 0.28	0.92, 0.87

<sup>a</sup> NF means that no residues were found, no signal on the chromatograph.

<sup>b</sup> <0.1 is less than the LOD of 0.1 ppm.

#### HED Comments/Conclusion:

Provided that a revised Section B/label is submitted as specified in Conclusion 2a, the submitted field trial data and geographic representation for non-bell pepper are adequate to satisfy the data requirements described in OPPTS 860.1500. Five non-bell pepper field trials were conducted in Regions I (1), II (1), III (1), VI (1), and X (1). All crops were treated with two applications of Select® 0.94 EC by ground spray at 0.25 lb ai/A for a total of 0.5 lb ai/A/season (1X). The first application was about 90 days after emergence or 60 days after transplanting. The second application was 14 days later and 20 days prior to harvest. The spray volume for the trials was between 30 and 75.6 GPA and included a tank-mixed crop oil concentrate at 1 qt/A or 1% v/v of the final spray. Clethodim residues were measured as DME and DME-OH. Residues in/on non-bell peppers ranged from 0.12 ppm to 0.92 ppm which supports the proposed tolerance of 1.0 ppm for residues of clethodim and its metabolites in/on the fruiting vegetables (except cucurbits) crop group.

Crop Group Tolerance

The petitioner has submitted field trial data for bell peppers, non-bell peppers and tomatoes to support a tolerance on the Fruiting Vegetables (except Cucurbits) crop group. The field trial data for bell pepper and non-bell pepper are adequate. However, the residue data for tomatoes are not adequate (PP#5F4572/5H5729, D219077, J. Morales, 12/11/95); and four additional field trials in California were required. The deficiency has not been resolved. HED still requires the four additional tomato field trial studies for establishment of a permanent tolerance on the Fruiting Vegetables (except Cucurbits) crop group. Therefore, a conditional registration for the Fruiting Vegetables (except Cucurbits) crop group is recommended.

OPPTS GLN 860:1520: Processed Food/Feed

No processing studies have been submitted with this petition. Two tomato processing studies were conducted (PP#5F4572/5H5729, D219077, MRID# 43757703, J. Morales, 12/11/95). The first trial was conducted in 1993 and was repeated in 1994 to obtain data for tomato puree. Two applications of clethodim were made at the rate of 1.25 lbs. ai/A (5X). Results are given in Table 11.

Table 11. Residues of Clethodim & its Metabolites in/on Tomato Processed Fractions

Commodity	Total Clethodim Equivalents (ppm)	Concentration Factor
Tomato Fruit	1.2	—
Paste	3.6	3.3X
Puree	2.6	2.2X

Based on the HAFT value (0.76 ppm), the expected residues should be 2.5 ppm for tomato paste (0.76 ppm x 3.3 = 2.5 ppm) and 1.7 ppm for tomato puree (0.76 ppm x 2.2 = 1.7 ppm).

HED Comments and Conclusions:

Time-limited tolerances for residues of clethodim and its metabolites in/on tomato paste at 3.0 ppm and tomato puree at 2 ppm have been established. The permanent tolerance for residues of clethodim and its metabolites in/on tomato paste and puree will be established when the additional tomato field trial data are submitted.

There are no regulated processed food or feed derived from the commodities associated with cucumbers, bell peppers and non-bell peppers.

OPPTS GLN 860.1480: Meat/Milk/Poultry/Eggs

No feeding studies have been submitted with this petition. As livestock feeds are not derived from cucumbers and the Fruiting Vegetables (except Cucurbits) crop group, secondary residues in/on livestock commodities are not expected to occur in/on livestock commodities. This use falls under 40 CFR 180.6(a)(3).

**OPPTS GLN 860.1850 and 860.1900: Confined/Field Accumulation in Rotational Crops**

A confined rotational crop study of [ring-4,6-<sup>14</sup>C]-clethodim with carrots, lettuce, and wheat (MRID 41030211) was previously conducted. The study was reviewed by E. B. Conerly (EFGWB Science Chapter for Clethodim, 06/26/1990). Results indicated that there is no need for field rotational crop trials. A 1- month plantback interval for crops rotated with alfalfa was specified (D 236382, M. Collantes, et. al, 2/10/98). The use directions submitted with the current petition do not specifically address rotational crops. The directions for use on fallow or nonproducing agricultural land is to not plant any crop for 30 days after application unless clethodim is registered for use on that crop. A revised Section B/label must be submitted which include a 1-month plantback restriction for all rotated crops without registered use.

**International Harmonization of Tolerances**

●8 Codex, Canadian, or Mexican maximum residue levels (MRLs) have been established or proposed for residues of clethodim in/on sugar beets (0.1 ppm), potatoes (0.2 ppm), rape seed (0.5 ppm), rape seed oils (0.5 ppm), sunflower seed (0.5 ppm), and sunflower seed oils (0.05 ppm). Some of these proposed tolerances have been recommended for withdrawal or reflect recent changes. See the *International Residue Limit Status* sheet. Harmonization could be an issue for Codex MRLs for potato/tuberous vegetables (0.2 ppm vs. 1.0 U.S.), sunflower seed (0.5 ppm vs. 5.0 ppm) and sunflower oils (0.05 ppm vs. 5.0 ppm U.S.). If a separate tolerance for refined sunflower oil was established at 0.1 ppm based on the submitted data, there would still be a Codex harmonization issue for both crude and refined sunflower oil. There could be a harmonization issue with the Canadian MRLs for potatoes (0.5 ppm vs. 1.0 ppm U.S.), sunflowers (0.2 ppm vs. 5.0 ppm U.S.), and rape/canola (0.05 ppm vs. 0.5 ppm U.S.). There are also current Codex harmonization concerns for clethodim residues in chicken meat, eggs, milk, sugar beets (roots), cottonseed, cottonseed oil, and dry bulb onions. There are no harmonization concerns for Mexican MRLs.

cc: RF, PP# 0E06097, Mxue, PM# 23, MRust  
RDI: ChemTeam:08/24/2000 :Sdapson 9/8/2000  
7509C: RAB3, MXue :CM-2: RM 810F: 703 305-6198: 9/8/2000

## CITATIONS

MRID 447532-03. Lai, J.C. and D. L. Kunkel (1998) Clethodim: Magnitude of the Residues on Cucumbers. IR-4 Project, Center for Minor Crop Pest Management, 681 U.S. Highway #1, South, North Brunswick, NJ 08902-3390 and Valent U.S.A. Corporation, 1333 North California Blvd., Suite 600, P.O. Box 8025, Walnut Creek, CA, 94596-8025. Performing Laboratory: IR-4 Project, Center for Minor Crop Pest Management, 681 U.S. Highway #1, South, North Brunswick, NJ 08902-3390 and Pesticide Research Center, Michigan State University, East Lansing, MI 48824-1311. Laboratory ID: 05219, December 18, 1998. 1 Volume, Unpublished.

MRID 447532-04. Lai, J.C., D. L. Kunkel, and K.S. Samoil (1998) Clethodim: Magnitude of the Residues on Bell Pepper. IR-4 Project, Center for Minor Crop Pest Management, 681 U.S. Highway #1, South, North Brunswick, NJ 08902-3390 and Valent U.S.A. Corporation, 1333 North California Blvd., Suite 600, P.O. Box 8025, Walnut Creek, CA, 94596-8025. Performing Analytical Laboratory: Valent Technical Center, Valent U.S.A. Corporation, Dublin, CA 94568, Laboratory ID: 5226, December 18, 1998. 2 Volumes, Unpublished.

MRID 447532-05. Lai, J.C., D. L. Kunkel, and K.S. Samoil (1998) Clethodim: Magnitude of the Residues on Pepper (Non-Bell). IR-4 Project, Center for Minor Crop Pest Management, 681 U.S. Highway #1, South, North Brunswick, NJ 08902-3390 and Valent U.S.A. Corporation, 1333 North California Blvd., Suite 600, P.O. Box 8025, Walnut Creek, CA, 94596-8025. Performing Analytical Laboratory: Valent Technical Center, Valent U.S.A. Corporation, Dublin, CA 94568, Laboratory ID: 5226, December 18, 1998. 2 Volumes, Unpublished.

INTERNATIONAL RESIDUE LIMIT STATUS			
<chem>CC1=CC=C(C=C1)C2=CC=CC=C2C3=CC=CC=C3C4=CC=CC=C4C5=CC=CC=C5C6=CC=CC=C6C7=CC=CC=C7C8=CC=CC=C8C9=CC=CC=C9C10=CC=CC=C10C11=CC=CC=C11C12=CC=CC=C12C13=CC=CC=C13C14=CC=CC=C14C15=CC=CC=C15C16=CC=CC=C16C17=CC=CC=C17C18=CC=CC=C18C19=CC=CC=C19C20=CC=CC=C20C21=CC=CC=C21C22=CC=CC=C22C23=CC=CC=C23C24=CC=CC=C24C25=CC=CC=C25C26=CC=CC=C26C27=CC=CC=C27C28=CC=CC=C28C29=CC=CC=C29C30=CC=CC=C30C31=CC=CC=C31C32=CC=CC=C32C33=CC=CC=C33C34=CC=CC=C34C35=CC=CC=C35C36=CC=CC=C36C37=CC=CC=C37C38=CC=CC=C38C39=CC=CC=C39C40=CC=CC=C40C41=CC=CC=C41C42=CC=CC=C42C43=CC=CC=C43C44=CC=CC=C44C45=CC=CC=C45C46=CC=CC=C46C47=CC=CC=C47C48=CC=CC=C48C49=CC=CC=C49C50=CC=CC=C50C51=CC=CC=C51C52=CC=CC=C52C53=CC=CC=C53C54=CC=CC=C54C55=CC=CC=C55C56=CC=CC=C56C57=CC=CC=C57C58=CC=CC=C58C59=CC=CC=C59C60=CC=CC=C60C61=CC=CC=C61C62=CC=CC=C62C63=CC=CC=C63C64=CC=CC=C64C65=CC=CC=C65C66=CC=CC=C66C67=CC=CC=C67C68=CC=CC=C68C69=CC=CC=C69C70=CC=CC=C70C71=CC=CC=C71C72=CC=CC=C72C73=CC=CC=C73C74=CC=CC=C74C75=CC=CC=C75C76=CC=CC=C76C77=CC=CC=C77C78=CC=CC=C78C79=CC=CC=C79C80=CC=CC=C80C81=CC=CC=C81C82=CC=CC=C82C83=CC=CC=C83C84=CC=CC=C84C85=CC=CC=C85C86=CC=CC=C86C87=CC=CC=C87C88=CC=CC=C88C89=CC=CC=C89C90=CC=CC=C90C91=CC=CC=C91C92=CC=CC=C92C93=CC=CC=C93C94=CC=CC=C94C95=CC=CC=C95C96=CC=CC=C96C97=CC=CC=C97C98=CC=CC=C98C99=CC=CC=C99C100=CC=CC=C100</chem>	Common Name: clethodim	<input checked="" type="checkbox"/> Proposed tolerance <input type="checkbox"/> Reevaluated tolerance <input type="checkbox"/> Other	Date: 05/08/200
<b>Codex Status (Maximum Residue Limits)</b>		<b>U. S. Tolerances</b>	
X No Codex proposal step 6 or above XNo Codex proposal step 6 or above for the crops requested #118 (see below)		Petition Number: 0E06097 DP Barcode: D268493 Other Identifier: EPA Reg. No. 59639-3, 59639-78	
Residue definition (step 8/CXL): [(E)-(±)-2-[1-[[3-chloro-2-propenyl)oxy]imino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one] and its metabolites containing the 5-(2-(ethylthio)propyl)cyclohexene-3-one and 5-(2-(ethylthio)propyl)-5-hydroxycyclohexene-3-one moieties and their sulphoxides and sulphones expressed as clethodim		Reviewer/Branch: Manying Xue/ RAB 3	
		Residue definition: [(E)-(±)-2-[1-[[3-chloro-2-propenyl)oxy]imino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one] and its metabolites containing the 5-(2-(ethylthio)propyl)cyclohexene-3-one and 5-(2-(ethylthio)propyl)-5-hydroxycyclohexene-3-one moieties and their sulphoxides and sulphones expressed as clethodim per 40 CFR 180.458	
Crop (s) <sup>1</sup>	MRL (mg/kg)	Crop(s)	Proposed Tolerance (ppm)
Fodder beet (stage 3)	0.1	Beets, sugar tops	1.0
Sugar beet (stage 6)	0.1		
Potato (stage 6)	0.2	Tuberous and corm vegetables (in tubers)	1.0
Sunflower seed (stage 6)	0.5	Potato flakes/granules	2.0
Sunflower oil-crude (stage 6, recommended for withdrawal)	0.05	Sunflower seed (includes sunflower oil)	5.0
Sunflower oil-edible (stage 6, recommended for withdrawal)	0.05	Sunflower meal	10.0
Rape seed (stage 6)	0.5	Canola/rape seed	0.5
Rape seed oil crude (stage 6, previously 0.05)	0.5	Canola meal (includes canola oils)	1.5
Rape seed oil edible (stage 6, previously 0.05)	0.5		

Limits for Canada		Limits for Mexico	
X No Limits X No limits for the crops requested		X No Limits XNo Limits for the crops requested	
Residue definition: Clethodim and metabolites containing the 2-cyclohex-1-enone moiety		Residue definition: Clethodim	
Crop(s)	MRL (mg/kg)	Crop(s)	MRL (mg/kg)
soybeans	10	Soya (soybean)	10
lentils	0.5		
peas (dry)	0.5		
potatoes	0.5		
mustard seed	0.4		
flax seed	0.3		
sunflower seed	0.2		
rape seed (canola)	0.05		
Notes/Special Instructions: Updated S. Funk 04/19/00. <sup>1</sup> For Codex, included only products related to current petition, additional MRLs are proposed or available.			