(2-8-96)

MEMORANDUM:

SUBJECT: **5F4572/5H5729**. Clethodim in/on Tomatoes and Tuberous and Corm Vegetables. Evaluation of Residue Data and Analytical Methodology. CBTS#'s 16,157, 16,158, and 16,442. DP Barcodes D219077, D219078, and D220698. MRID#'s 437577-01, 437577-02, 437577-03, 437577-04.

FROM: José J. Morales, Chemist
Tolerance Petition Section II
Chemistry Branch I -- Tolerance Support
Health Effects Division (7509C)

THROUGH: Ed Zager, Acting Chief
Chemistry Branch I -- Tolerance Support
Health Effects Division (7509C)

TO: Joanne I. Miller/Dan Kenny, PM 23
Fungicide-Herbicide Branch
Registration Division (7505C)
and
Karen Whitby, Section Head
Registration Section
RCAB (7509C)

Valent U.S.A. originally requested the establishment of tolerances for the combined residues of the herbicide 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, expressed as clethodim, in/on tuberous and corm vegetables at 1 ppm; tomatoes at 1 ppm; potato, dry peel at 2 ppm; potato, flakes and granules at 2 ppm; tomato, dry pomace at 3 ppm; tomato, puree at 2 ppm; and tomato, paste at 3 ppm.

The petitioner has submitted an amendment to this petition. In a letter dated 9/28/95, Valent is requesting to withdraw all uses except tomatoes. They have submitted new labels to reflect this use and they have mentioned that they will resubmit the withdrawn uses at a later date. A revised Section F proposing tolerances for residues of clethodim in/on tomatoes at 1 ppm; tomato puree at 2 ppm; and tomato paste at 3 ppm was submitted with this amendment.

Permanent tolerances were established for the combined residues of the herbicide clethodim and its metabolites containing the 2-cyclohexen-1-one moiety under 40 CFR

CLETHODIM.MEMO

§180.458 for the fat, meat, and mbyp of cattle, goats, hogs, horses, poultry, and sheep at 0.20 ppm; milk at 0.05 ppm; eggs at 0.20 ppm; cottonseed at 1.0 ppm; and soybeans at 10.0 ppm.

Feed additive tolerances were established for the combined residues of the herbicide clethodim and its metabolites containing the 2-cyclohexen-1-one moiety under 40 CFR §186.1075 for cottonseed meal at 2.0 ppm; and soybean soapstock at 15.0 ppm.

CONCLUSIONS

1. The manufacturing process of technical grade clethodim has been adequately described. We do not foresee any residue problems from impurities in the technical.

2. CBTS concludes that the registrant has proposed an adequate set of directions for use of Select® 2 EC and Select® on tomatoes.

3a. CBTS concludes that the nature of the residue in plants is adequately understood for the purposes of the subject petition. Studies have been conducted in a root crop (carrots) and two oilseeds (soybean and cotton). The residue of concern is clethodim and its metabolites containing the 2-cyclohexen-1-one moiety. However, the petitioner should be reminded that for future petitions on crops other than root crops, legumes, or oil seeds additional metabolism data should be provided on a crop such as a leafy vegetable, or fruit crop. Until there are plant metabolism data for clethodim on at least 3 widely different representative commodities; e.g., tree nut, leafy vegetable, small grain, legume, root/tuber crop, oil seed, etc., which reflect a similar metabolism profile, CBTS can not conclude that the nature of the residue is understood in all plants.

3b. No Secondary residues are anticipated from the proposed use since no animal feed items are involved. Therefore, the nature of the residue in ruminants and poultry is not of concern for this use.

4a. Analytical methods are available for enforcement. Method EPA-RM-26D-2, "Confirmatory Method for the Determination of Clethodim and Clethodim Metabolites in Crops, Animal Tissues, and Milk and Eggs", which distinguishes clethodim residues from residues of the structurally similar herbicide Poast®, and method RM-26B-2 ,"Analytical Method for the Determination of Clethodim Residues", the common moiety method, have undergone successful EPA Method Validation.

4b. CBTS concludes that adequate validation data have been submitted for clethodim and its metabolites in tomatoes using the compound specific method EPA-RM-26D-2. An adequate amount of chromatographic data and raw data have been submitted by the petitioner to demonstrate that this method will separate clethodim from sethoxydim in tomatoes.

5. Adequate recoveries of clethodim, clethodim sulfoxide, and 5-OH clethodim sulfone have been obtained under FDA's multiresidue protocols (PP#9F3743, M. Nelson's memo of 3/12/90).

6. CBTS concludes that total clethodim residues are stable in tomatoes stored frozen (-20°C) for up to 13 months.

7. CBTS cannot draw any conclusion on the adequacy of the proposed tolerance on tomatoes at this time. Based on the 6/2/94 Field Trial Document, a total of 16 field trial sites (12 if no residues are detected) are required for the registration of a chemical in/on tomatoes. The document indicates that of the 16 field trials, 11 should be conducted in the state of California. Based on the fact that only 3 studies in the state of California were submitted by the petitioner, and that the highest residue value found was in one of these field trials, CBTS cannot recommend for a permanent tolerance at this time. However, pending submission of 4 field trials in the state of California, conducted at the maximum use rate and proposed PHI, CBTS can recommend for the establishment of Time Limited Tolerances for residues of clethodim in/on tomatoes at 1 ppm.

8. The tolerance levels proposed for tomato paste and puree are appropriate. However, based on current Agency policy, Section 409 food additive tolerances are not appropriate for these not ready-to-eat commodities. The Agency will establish Maximum Residue Limits (MRL's) under Section 701 of the FFDCA.

   Pending resolution of the residue data deficiencies in Conclusion 7, CBTS can recommend for the establishment of Time Limited MRL's for residues of clethodim in/on tomato processed products.

9. According to the Updated Livestock Feeds Table for Subdivision O (date 9/12/95), no animal feed items are associated with tomatoes. Therefore, no secondary residues in animals are anticipated from the proposed use.

10. An international residue limits (IRL) status sheet is attached to this review. There are no Codex, Canadian or Mexican Limits established for clethodim on tomatoes. Therefore, no compatibility problems exist.

RECOMMENDATION

Pending resolution of the residue data deficiencies (Conclusion 7), CBTS can recommend for the establishment of Time Limited Tolerances for residues of clethodim in/on tomato commodities. For puree and paste Maximum Residue Limit (MRL's) need to be established under Section 701 of the FFDCA. RD should contact OGC with regard to procedures for setting 701 MRL's.

CBTS recommends for the following Time Limited Tolerances:

Tomatoes at 1 ppm (Section 408 tolerance)
Tomato, puree at 2 ppm (Section 701 MRL)
Tomato, paste at 3 ppm (Section 701 MRL)

A DRES analysis can be initiated using 1 ppm for tomato juice and canned tomatoes, 2 ppm for tomato puree and catsup, and 3 ppm for tomato paste.

DETAILED CONSIDERATIONS

PRODUCT CHEMISTRY

The manufacturing process for clethodim was submitted in support of PP#9F3743 (MRID#'s 409745-01 thru -05) and discussed in M. Nelson's memo of 3/12/90. There are no toxicological concerns for any of clethodim impurities.

CBTS concludes that the manufacturing process of technical grade clethodim has been adequately described. We do not foresee any residue problems from impurities in the technical.

PROPOSED USE

Two registered formulations of clethodim are proposed for use: Select® 2 EC and Select® Herbicide. Select® 2 EC Herbicide (EPA Reg. No. 59639-3) is an emulsifiable concentrate containing 25% of ai and 75% of inerts. This formulation contains 2 pounds of ai per gallon. Select® Herbicide (EPA Reg. No. 59639-78) contains 12.6% of ai and 87.4% of inerts. The formulation contains 0.94 pounds of ai per gallon.

The registrant proposes use of Select® 2 EC herbicide for postemergence control of annual and perennial grasses in tomatoes. To control annual grasses apply Select® 2 EC at the rate of 4 fl. ozs./A (0.064 lbs. ai/A) to 16 fl. ozs./A (0.25 lbs. ai/A) by ground application in a minimum of 5 gallons and a maximum of 40 gallons of spray solution per acre. Air application should be made in a minimum of 3 gallons of spray solution per acre. Increase spray volume up to 10 gallons as grass or crop foliage becomes dense. To control perennial grasses apply at the rate of 6 fl. ozs./A (0.096 lbs. ai/A) to 16 fl. ozs./A (0.25 lbs. ai/A) by ground application in a minimum of 5 gallons and a maximum of 40 gallons of spray solution per acre. Air application should be made in a minimum of 3 gallons of spray solution per acre. Increase spray volume up to 10 gallons as grass or crop foliage becomes dense. Apply only to actively growing grasses. Always use a crop oil concentrate containing at least 15% emulsifier at 1% v/v to the finished spray volume. Make second application to actively growing grass 2 to 3 weeks after emergence of new growth. The registrant also proposes a spot application treatment using Select® 2 EC and a crop oil concentrate at a 1:2 ratio (fl. oz:fl. oz). The PHI for tomatoes is 20 days. Do not exceed a total of 32 fl. ozs./A (0.50 lbs. ai/A) of Select® 2 EC herbicide per season.

The registrant proposes use of Select® herbicide for postemergence control of annual and perennial grasses in tomatoes. To control annual grasses apply Select® at the rate of 8 fl. ozs./A (0.06 lbs. ai/A) to 34 fl. ozs./A (0.25 lbs. ai/A) by ground application in a minimum of 5 gallons and a maximum of 40 gallons of spray solution per acre. Air application should be made in a minimum of 3 gallons of spray solution per acre. Increase spray volume up to 10 gallons as grass or crop foliage becomes dense. To control perennial grasses apply at the rate of 13 fl. ozs./A (0.09 lbs. ai/A) to 34 fl. ozs./A (0.25 lbs. ai/A) by ground application in a minimum of 5 gallons and a maximum of 40 gallons of spray solution per acre. Air application should be made in a minimum of 3 gallons of spray solution per acre. Increase spray volume up to 10 gallons as grass or crop foliage becomes dense. Apply only to actively growing grasses. Always use a crop oil concentrate containing at least 15% emulsifier at 1% v/v to the finished spray volume. Make second application to actively growing grass 2 to 3 weeks after emergence of new growth. The registrant also proposes a spot application treatment using Select® and a crop oil concentrate at a 1:2 ratio (fl. oz:fl. oz). The PHI for tomatoes is 20 days. Do not exceed a total of 68 fl. ozs./A (0.50 lbs. ai/A) of Select® herbicide per season.

CBTS concludes that the registrant has proposed an adequate set of directions for use of Select® 2 EC and Select® on tomatoes.

NATURE OF THE RESIDUE

No new metabolism studies were submitted for clethodim.

Plants

A metabolism study in carrots, soybeans, and cotton was submitted with PP#9F3743 (MRID#410301-37) and discussed in M. Nelson's memo of 3/12/90. Immature plants of carrots, soybeans, and cotton were treated twice at a 14-day interval with a 50:50 tautomeric mixture of ring [6-^{14}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 preharvest intervals of 20, 30, and 70 days. The major metabolic pathways of clethodim (C) in plant were initial sulfoxidation to clethodim sulfoxide (CSO) followed by further oxidation to clethodim sulfone (CSO_2), elimination of the chloroallyloxy side chain to give the imine sulfoxide (ISO) and sulfone (ISO_2), and hydroxylation to form the 5-OH sulfoxide (5OH-SO) and sulfone (5OH-SO_2). Clethodim sulfoxide and clethodim sulfone conjugates were also detected as major or minor metabolites, depending on plant species and subfractions. 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 ^{14}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 $^{14}CO_2$).

CBTS concludes that the nature of the residue in plants is adequately understood for the purposes of the subject petition. Studies have been conducted in a root crop (carrots) and two oilseeds (soybean and cotton). The residue of concern is clethodim and its metabolites containing the 2-cyclohexen-1-one moiety. However, the petitioner should be reminded that for future petitions on crops other than root crops, legumes, or oil seeds additional metabolism data should be provided on a crop such as a leafy vegetable, or fruit crop. Until there are plant metabolism data for clethodim on at least 3 widely different representative commodities; eg, tree nut, leafy vegetable, small grain, legume, root/tuber crop, oil seed, etc., which reflect a similar metabolism profile, CBTS can not conclude that the nature of the residue is understood in all plants.

Animals

No Secondary residues are anticipated from the proposed use since no animal feed items are involved. Therefore, the nature of the residue in ruminants and poultry is not of concern for this use.

ANALYTICAL METHODOLOGY

The analytical method used to gather the magnitude of the total clethodim residue data on tomatoes was Chevron Chemical Method RM-26B-1, "Analytical Method for the

Determination of Clethodim Residues". This method is one of 2 methods recommended to enforce the clethodim tolerances. The registrant has revised this method at CBTS's request and designated the revision as Method RM-26B-2 (MRID#413899-01). This revised method has successfully completed a Petition Method Validation (PMV) in EPA Laboratories (M. Nelson's memo of 5/4/90). Briefly, 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_2Cl_2, and determination by GC-FPD-S. The total residue is expressed as clethodim equivalents. The limit of quantitation is 0.10 ppm. The minimum detection limit for residues measured as the dimethyl esters is 0.01 ppm for milk; 0.05 ppm for other animal commodities including eggs; and 0.05 ppm for crops.

The second method recommended to enforce clethodim tolerances is the compound specific residue analytical method, EPA-RM-26D-2, "Confirmatory Method for the Determination of Clethodim and Clethodim Metabolites in Crops, Animal Tissues, and Milk and Eggs" (MRID#429245-02). This method distinguishes clethodim residues from residues of the structurally similar herbicide Poast®, which contains sethoxydim as the active ingredient. The registrant has revised and rewritten this compound specific method as ACB has suggested and has included additional modifications from current method development. This method has successfully completed a Petition Method Validation (PMV) in EPA Laboratories (F. Griffith's memo of 9/29/93). In summary, a 50 gram sample is extracted with 150-200 mL of methanol/water (1/4, v/v), filtered through Whatman # 42 paper, and precipitated with 2 grams of calcium hydroxide. The solution is partitioned 3 X 100 mL CH_2Cl_2, dried through a bed of anh. Na_2SO_4, and rotary evaporated to just dry. The derivatized solution is base washed with 10 mL of 0.1N NaOH, then methylated with CH_2N_2 with silica gel catalysis before it is oxidized with 2 mL of a 10% solution of m-chloroperbenzoic acid. The solution is quenched with 10% sodium thiosulfate, washed with sat. sodium bicarbonate solution, dried through anh. sodium sulfate, and concentrated with a rotary evaporator. Clean-up is through a 10 gram silica-gel column with the clethodim metabolites eluted off in 200 mL of acetone:methylene chloride (3/7, v/v). Determination is by HPLC using a Hewlett-Packard, model 1090 HPLC, equipped with a Hypersil ODS, 3 um, 15 cm X 4.6 mm column. The mobile phase is a water-ACN gradient at a flow rate of 1 ml per min. The detector is UV at 266 mn with 254 mn as the alternate wavelength. The petitioner's data show the limit of quantitation (LOQ) is 0.05 ppm for crops and tissues, and 0.02 ppm for milk. Quantification is by external standards. The minimum detection limit (MDL) is 0.03 ppm for crops and 0.01 ppm for milk. This method has been shown to be suitable to be a quantitative procedure to enforce the total clethodim tolerances in crops and animal tissues. The method is a qualitative confirmatory method for total clethodim tolerances in milk. However, this method is not quantitative for milk and is not suitable for enforcing the total clethodim tolerance in milk. The common moiety method, RM-26B-2, is quantitative for milk and is the enforcement method for milk (F. Griffith's memo of 9/29/93).

As noted in F. Griffith's memo of 11/16/92, company generated method validation data are required for any new total clethodim tolerance (s) on all matrices; ie, the rac (s), food and/or feed processed commodities, and if appropriate for meat, milk, poultry, and eggs, on which tolerances are proposed. These company generated validation data are necessary for both the common moiety method and the compound specific method. Therefore, in support of the subject tolerance petition, the petitioner submitted the following reports:

> "Determination of Clethodim Residues in Tomato by the Confirmatory Method, EPA-RM-26D-2"; 5/23/95; J. C. Lai; Laboratory Project ID: VP10911; Performing Laboratory was Valent U.S.A. Corporation, Valent Dublin Laboratory, Dublin, CA (MRID# 437577-02).

Tomato macerates were used at four fortification levels: the limit of quantitation (0.20 ppm), one half the proposed tolerance (0.50 ppm), the proposed tolerance level (1.0 ppm), twice the proposed tolerance (2.0 ppm), with both hydroxylated and unhydroxylated clethodim moieties. At the projected tolerance level, sethoxydim metabolites were concurrently analyzed to demonstrate that these moieties did not interfere with the determination of clethodim residues. the following minor modifications were made to the method: a) smaller aliquots of matrices were analyzed, b) the volume of base and water used in the partition step following methylation was increased, and c) HPLC parameters were adjusted to enhance quantitation. In all experiments, duplicate analysis were conducted for the untreated control and fortified samples. Recoveries for fortified tomato macerates are shown in Table I. No residues were found in the control samples.

Table I. Clethodim and Sethoxydim Recoveries in Tomatoes Using the Unmodified Method EPA-RM-26D-2

Fortification Level (ppm)	Percent Recovery			
	CS[1]	5-OHCSO$_2$[2]	SS[3]	5-OHSSO$_2$[4]
0.20	92,79	92,82	--	--
0.50	78,76	86,76	--	--
1.0	89,82	100,87	108,97	131,92
2.0	90,91	101,94	--	--

1- Clethodim
2- 5-Hydroxy Clethodim Sulfone
3- Sethoxydim
4- 5-Hydroxy Sethoxydim Sulfone

CBTS concludes that adequate validation data have been submitted for clethodim and its metabolites in tomatoes using the compound specific method EPA-RM-26D-2. An adequate amount of chromatographic data and raw data have been submitted by the petitioner to demonstrate that this method will separate clethodim from sethoxydim in tomatoes

MULTIRESIDUE TESTING

The petitioner has determined recoveries of clethodim, clethodim sulfoxide, and 5-OH clethodim sulfone under FDA's multiresidue protocols (PP#9F3743, M. Nelson's memo of 3/12/90).

RESIDUE DATA

Residue data reflecting the application of clethodim to tomatoes appear in the following report:

> "Magnitude of Clethodim Residues in Tomatoes - Raw Agricultural Commodities and Processed Parts"; J. C. Lai; 5/23/95; Laboratory Project ID No. V10688; Performing Laboratory was Valent U.S.A. Corporation, Valent Dublin Laboratory, Dublin, CA (MRID# 437577-03).

Twelve field trials on tomatoes were conducted, six in 1993 and six in 1994. The 1993 field trials were conducted in CA (2), FL (1), IN (1), NJ (1), and OH (1). The 1994 field trials were conducted in CA (1), MI (1), FL (1), OH (1), PA (1), and SC (1). The formulation used in both trials was Select® herbicide. In all trials, two applications were made, at 14 day intervals between each, using ground equipment, at the rate of 0.25 lbs. ai/A with PHI's ranging from 15 to 30 days. Duplicate samples of treated tomatoes were collected from each

trial. After collection, samples were frozen and shipped to Valent U.S.A. Corporation, Valent Dublin Laboratory, Dublin, CA.

A freezer storage stability study was conducted using frozen (-20°C) tomato macerates fortified with 0.50 ppm clethodim and 0.50 ppm 5-OH clethodim sulfone. Reanalysis of these samples at intervals of 0, 3, 5, 11, and 13 months resulted in clethodim recoveries (as DME) which ranged from 71% to 93%. 5-OH clethodim sulfone recoveries (as DME-OH) ranged from 80% to 105%. Tomato samples were analyzed for total clethodim residues up to 11 months after sampling. Maximum interval between extraction and analyses was 8 days.

CBTS concludes that total clethodim residues are stable in tomato macerates stored frozen (-20°C) for up to 13 months.

Recovery data were obtained from untreated samples of tomatoes, analyzed concurrently with the field trial samples, fortified with clethodim at the level of 0.50 ppm to 1.0 ppm. Overall recoveries of 64% to 84% were obtained. Recovery data for 5-OH clethodim sulfone at fortification levels of 0.50 ppm to 1.0 ppm were 75% to 110%. Recovery data for clethodim sulfoxide at fortification levels of 0.50 ppm to 1.0 ppm were 79% to 91%. Submitted chromatograms show well resolved peaks in support of these data.

Table II summarizes the amount of residues on tomatoes resulting from 2 applications of clethodim at the rate of 0.25 lbs. ai/A.

Table II. Clethodim Residues on Tomatoes

Field Trial Location	PHI	Clethodim Equivalents (ppm)		
		DME (ppm)[1]	DME-OH (ppm)[2]	Total (ppm)
CA (1993)	15	0.56 0.94	0.29 0.50	0.85 1.4
	20	0.49, 0.48 0.54, 0.50	0.27, 0.23 0.28, 0.26	0.76, 0.71 0.82, 0.76
	30	0.34 0.44	0.20 0.20	0.54 0.64
CA (1993)	20	0.15 0.16	<0.1 <0.1	0.15 0.16
	20[3]	0.69 0.77	0.40 0.38	1.1 1.2

10

Field Trial Location	PHI	Clethodim Equivalents (ppm)		
		DME (ppm)[1]	DME-OH (ppm)[2]	Total (ppm)
FL (1993)	15	<0.1 <0.1	<0.1 <0.1	<0.1 <0.1
	20	0.35 0.15	<0.1 <0.1	0.35 0.15
	30	<0.1 <0.1	<0.1 <0.1	<0.1 <0.1
OH (1993)	15	0.20 0.25	<0.1 <0.1	0.20 0.25
	20	0.24 0.27	0.1 <0.1	0.34 0.27
	30	0.18 0.18	<0.1 <0.1	0.18 0.18
NJ (1993)	21	0.26 0.24	0.20 0.19	0.46 0.43
IN (1993)	20	<0.1 <0.1	0.12 0.11	0.12 0.11
SC (1994)	20	0.20 0.20	0.15 0.15	0.35 0.35
FL (1994)	20	<0.1 <0.1	<0.1 <0.1	<0.1 <0.1
CA (1994)	20	0.44 0.34	0.21 0.20	0.65 0.54
OH	20	0.17 0.21	<0.1 <0.1	0.17 0.21
	20[3]	1.2 0.96	0.50 0.39	1.7 1.4

11

Field Trial Location	PHI	Clethodim Equivalents (ppm)		
		DME (ppm)[1]	DME-OH (ppm)[2]	Total (ppm)
PA	20	0.31 0.29	0.21 0.21	0.52 0.50
MI	20	<0.1 <0.1	<0.1 <0.1	<0.1 <0.1

1 and 2 - acronyms for the dimethyl esters of 3-[2-(ethylsulfonyl) propyl]pentanedioic acid and 3-[2-(ethylsulfonyl)propyl]-3-hydroxypentanedioic acid, respectively.

3. Applications were made at the rate of 1.25 lbs. ai/A (5X) for processing studies.

The petitioner stated that the limit of detection was 0.10 ppm. As can be seen from the Table, the maximum residue level found in tomatoes using the 0.94 EC formulation at the proposed PHI of 20 days and application rate of 0.25 lbs. ai/A was 0.82 ppm. Control samples showed no detectable clethodim equivalents.

CBTS cannot draw any conclusion on the adequacy of the proposed tolerance on tomatoes at this time. Based on the 6/2/94 Field Trial Document, a total of 16 field trial sites (12 if no residues are detected) are required for the registration of a chemical in/on tomatoes. The document indicates that of the 16 field trials, 11 should be conducted in the state of California. Based on the fact that only 3 studies in the state of California were submitted by the petitioner, and that the highest residue value found was in one of these field trials, CBTS cannot recommend for a permanent tolerance at this time. However, pending submission of 4 field trials in the state of California, conducted at the maximum use rate and proposed PHI, CBTS can recommend for the establishment of Time Limited Tolerances for residues of clethodim in/on tomatoes at 1 ppm.

PROCESSED COMMODITIES

A report of residues resulting from the processing of tomatoes is included in the following submission:

> "Magnitude of Clethodim Residues in Tomatoes - Raw Agricultural Commodities and Processed Parts"; J. C. Lai; 5/23/95; Laboratory Project ID No. V10688; Performing Laboratory was Valent U.S.A. Corporation, Valent Dublin Laboratory, Dublin, CA (MRID# 437577-03).

Two tomato processing studies were conducted. 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 the label rate). After collection, tomato samples were frozen and shipped to William Englar and Associates, where they were processed into wet pomace, dry pomace, paste, and juice. For the 1994 trial, puree was added to the commodity list (the complete processing procedure is given on page 182 of the report). The petitioner stated that processed fractions were analyzed within 6 months of their generation. Overall recovery values were from 84 to 96% for the samples analyzed up to 7 months after collection and stored at -20°C.

The procedure used to calculate the concentration factors reflects the revised CBTS policy for determining the need for Section 409 Tolerances and 701 MRLs (memo dated 7/17/95). Briefly, instead of using the Section 408 tolerance for calculating the residue level in processed commodities (in other words, the concentration factor multiplied by the rac tolerance), the highest average field trial ("HAFT") value will be used. This "HAFT" value will be multiplied by the concentration factor or average concentration factor (if there is more than one processing study) to obtain the residue level in the processed commodity.

Results are given in Table III.

Table III. Clethodim Residues Found in Processed Fractions of Tomatoes

Commodity	Average Clethodim Equivalents (ppm) for 1993[1] (concentration factor)	Total Clethodim Equivalents (ppm) for 1994[2] (concentration factor)	Average Concentration Factor
Tomato Fruit	0.84	1.2	--
Wet Pomace	0.79 (0.94X)	1.0 (0.83X)	0.89X
Dry Pomace	2.55 (3X)	4.0 (3.3X)	3.2X
Paste	2.9 (3.5X)	3.6 (3X)	3.3X
Juice	0.76 (0.9X)	0.92 (0.77X)	0.84X

Commodity	Average Clethodim Equivalents (ppm) for 1993[1] (concentration factor)	Total Clethodim Equivalents (ppm) for 1994[2] (concentration factor)	Average Concentration Factor
Puree	--[3]	2.6 (2.2X)	2.2X

1. Duplicate samples were analyzed.
2. Only one sample was analyzed.
3. Puree was not analyzed.

According to Table II (9/12/95), dry pomace is not a significant feed item anymore. Therefore, it will not be included in the following discussion. Tomato puree and paste are considered not-ready to eat commodities. Therefore, in order to determine whether a 701 MRL or a 409 tolerance will be needed the following procedure was used:

a) Determination of the HAFT: the field trial with the highest residue value was used. Inspection of Table II above shows that for the 1993 CA field trial the following values were obtained: 0.76 ppm, 0.71 ppm, 0.82 ppm, and 0.76 ppm. The HAFT is determined by averaging these values. The HAFT value is 0.76 ppm.

b) The average concentration factor is multiplied by the HAFT. For tomato paste:

0.76 ppm x 3.3 = 2.5 ppm

For tomato puree:

0.76 ppm x 2.2 = 1.7 ppm

c) Since the residue in paste and puree exceed the rac tolerance of 1 ppm, these will be divided by a dilution factor to determine the residue level in the ready-to eat food:

for tomato paste: 2.5/2.5 = 1 ppm

for tomato puree: 1.7/1.5 = 1.1 ppm

The dilution factors of 2.5 for paste and 1.5 for puree are based on the recipe files in USDA's Survey Systems/Food Consumption Laboratory of the Beltsville Human Nutrition Center.

d) Since the residues in the ready-to eat foods do not appreciably exceed the rac tolerance of 1.0 ppm, Section 701 MRL's will be needed for tomato paste and tomato puree.

CBTS concludes that the petitioner does not need to submit a revised Section F proposing 701 maximum residue limit tolerances for the tomato processed commodities puree and paste. The establishment of these MRL's under Section 701 of the FFDCA can be handled by the Federal Register Notices prepared by the Agency.

Pending resolution of the residue data deficiencies, CBTS can recommend for the establishment of Time Limited Maximum Residue Limits for residues of clethodim in/on tomato processed products.

MEAT, MILK, POULTRY AND EGGS

According to the Updated Livestock Feeds Table for Subdivision O (date 9/12/95), no animal feed items are associated with tomatoes. Therefore, no secondary residues in animals are anticipated from the proposed use.

OTHER CONSIDERATIONS

An international residue limits (IRL) status sheet is attached to this review. There are no Codex, Canadian or Mexican Limits established for clethodim on tomatoes. Therefore, no compatibility problems exist.

Attachment: International Residue Limit Status Sheet

cc: RF, Circu., José J. Morales, E. Haeberer, PP#5F4572/5H5729
7509C: Reviewer (JJM): CM#2: Rm 804-Q: 305-5010: typist (JJM): 12/11/95
RDI: R. Loranger (2/6/96): E. Zager (2/7/96): E. Haeberer (12/15/95)