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

MAY 10 1991

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

Subject: PP9F3743 - Clethodim (Select®) in/on Soybeans, Cottonseed, and Animal Commodities.
Revised Petition Method Validation Request for Confirmatory Method.
(MRID# 417307-01 and 416234-2) [No DEB No.]
(No HED Project No.)

From: Francis D. Griffith, Jr., Chemist
Chemistry Branch I - Tolerance Support
Health Effects Division (H-7509C)

Thru: Richard D. Schmitt, Ph.D., Chief
Chemistry Branch I - Tolerance Support
Health Effects Division (H7509C)

To: Donald A. Marlow, Chief
Analytical Chemistry Branch
Biological and Economic Analysis Division (H7503W)

Valent U.S.A. Corporation has proposed the establishment of revised tolerances for combined residues of the herbicide Clethodim and its metabolites in cottonseed, soybeans, and animal commodities. As a result of the EPA-Valent conference of April 16, 1991, and several telephone conversations afterward, CBTS has decided to revise its petition method validation (PMV) request for the clethodim confirmatory method, RM-26D-1.

This PMV request is designed to supersede the request of February 22, 1991, for compounds and levels not previously tested. CB reiterates those parts of the February 22, 1991, PMV request that ACB indicated in its March 26, 1991 memo could be completed are to be completed.

The revised PMV is for Method RM-26D-1 (MRID# 417302-01) which was sent to you as Attachment 4 in our February PMV request. The petitioner has provided additional method validation data in MRID# 416234-02, titled "Confirmatory Method for the Determination of Clethodim and Clethodim Metabolism Crops, Animal Tissues, Milk, and Eggs. Supplemental to: Confirmatory Metabolites in Crops" by B. Ho and dated August 23,

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1990. Two copies of these data are attached to this memorandum as Attachment 2.

This PMV for Method RM-26D-1 is designed to show it can separate clethodim DME from sethoxydim DME. CB is aware recoveries are less than 70% in several instances. However, this is not an issue as the common moiety method, RM-26B-2 is a quantitative procedure. This method has recently completed a successful PMV (see memo by F.D. Griffith, Jr., dated April 19, 1991).

This revised PMV request is not our final PMV request for the Clethodim confirmatory method RM-26D-1. It covers only those portions of the PMV for which the petitioner has presented adequate recovery data and chromatographic support. ACB should be aware that CBTS has requested method validation data from Valent for S-methyl clethodim sulfoxide in milk at the 0.02 ppm and 0.05 ppm levels. These data have been submitted to the Agency and are in the process of being routed to CBTS for review.

The revised PMV for the confirmatory method RM-26D-1 is for 4 chemicals (clethodim sulfoxide, 5-hydroxyclethodim sulfoxide, and corresponding sethoxydim analogs) in soybeans, beef liver, and milk.

All samples (including controls) should be run in duplicate at the requested fortification levels (see Attachment I, Table).

The standards procured for the February 22, 1991, PMV request on Method RM-26B-2 are the same ones necessary for this revised PMV request for method RM-26D-1.

The Registration Division Product Manager, Joanne Miller, should be contacted directly concerning the priority for completion of the PMV for which data have been submitted, and completion of the total PMV request.

Please return the requested PMV information on the attached Method Report Form, and all other information concerning the PMV that are generated according to our SOP on PMVs, including fortified samples, standard curves, and examples of sample calculations. A copy of any clethodim method or recovery data supplied directly to ACB by Valent U.S.A. for this PMV should be returned to CBTS with your final report. CB also requests that in your PMV report a summary of company contacts be provided to include the cause of the contact and what changes, if any, were made in the method.

Please address your written report to: Robert S. Quick, Section Head, Tolerance Petition Section I, Chemistry Branch I - Tolerance Support, Health Effects Division (H-7509C)

ATTACHMENTS

1. Method Report Form (2 pages)
2. "Confirmatory Method for the Determination of Clethodim and Clethodim Metabolites in Crops, Animal Tissue, Milk and Eggs. Supplemental to: Confirmatory Method for Determination of Clethodim Metabolites in Crops," by B. Ho, dated August 1990, MRID# 416234-02. 122 pages.

cc (with all attachments):
P. Cornelíussen (FDA, HFF-426),
R. Ellis (USDA, FSIS).

cc (with Attachment 1 only):
R.F., Circ(7), Reviewer (FDG), PP#9F3743, M. Bradley (MTO File/PAM-II Co-Editor), J. Miller (PM-23, H.K. Hundley (ACB/BEAD), R. Thompson (RTP-NC).

H7509C:CBTS:Reviewer(FDG):CM#2:RM-814B: 557-0826:vg:5/8/91:
edit:fdg:5/9/91.

RDI:SecHd:RSQuick:5/9/91:BrSrSci:RALoranger:5/9/91.

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ATTACHMENT 1

METHOD - Valent Analytical Method

"Confirmatory Method for the Determination of Clethodim and Clethodim metabolites in Crops, Animal Tissues, Milk and Eggs," Method R-M-26D-1 J.C. Lai, December 14, 1990, 18 pages MRID#417307-01.

Please do not use control values for recovery corrections.

Please do not report control values as 0.0 ppm. Accurately state your limit or detection and note any commodity co-extractives that could change the recovery values reported. Also please confirm the petitioner's claims for his limits of detection in soybeans at 0.05 ppm and in milk at 0.02 ppm.

Commodity	Chemicals Added	*Each Compound ppm Added	Individual ppm Found	% Recovery
Soybeans	CSO + 50H-CSO	0.0 (Control)		
		0.05		
		1.0		
		5.0		
	CSO + 50H-CSO + SSO	5.0		
	CSO + 50H-CSO + 50H-SSO	5.0		
Beef Liver	CSO	0.0 (Control)		
		0.2		
	CSO + SSO	0.2		
Milk	CSO	0.0 (Control)		
		0.02		
		0.05		
	CSO + SSO	0.05		

* CSO = Clethodim Sulfoxide, 5OH-CSO = 5-Hydroxy Clethodim Sulfoxide, SSO = Sethoxydim Sulfoxide, 5OH-SSO = 5 Hydroxy Sethoxydim Sulfoxide.

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Modifications to Method (Major or Minor):

Special Precautions to be Taken:

Sources of Analytical Standards:

If derivatized Standard use, give source;

Instruments for confirmation:

If instrument parameters differ from method given, please list parameters used:

Commercial Source for any special Chemicals or Apparatus:

Comments

Chromatograms