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

NOV - 1 1991

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

SUBJECT: PP#9F03743/FAP#1H05614. Clethodim (Select® 2EC Herbicide) in or on soybeans, cottonseed and animal commodities.
RD submission of 10/30/91: Response to comments by OGC.
MRID No.: None, CB No.: 8796.
DP Barcode: D170442

FROM: William D. Wassell, Chemist
Tolerance Petition Section I
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10/31/91

THROUGH: R. W. Cook, Acting Section Head
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TO: Joanne Miller, PM - 23
Fungicide-Herbicide Branch
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and

Toxicology Branch II - HFA Support
Health Effects Division (H7509C)

Summary/Background:

CBTS has conditionally recommended for the establishment of tolerances with an expiration date, for the combined residues of clethodim and its metabolites containing the 2-cyclohexen-1-one moiety in or on soybean, cottonseed and animal commodities at various levels. RD requests clarification of CBTS's requirements for a permanent tolerance and to answer two questions posed by J. Fleuchaus of OGC.

J. Fleuchaus has inquired:

Why is it acceptable to establish this tolerance without an acceptable method? What is

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the basis for registration here? Since this is a new chemical we cannot register conditionally where there is no adequate method.

CBTS response:

To answer these questions, CBTS will briefly summarize the events leading up to our current position on the subject petitions.

Dr. M.J. Nelson of CBTS conducted the initial Residue Chemistry Review of clethodim, dated 3/12/90. In the original submission, Valent U.S.A Corporation proposed a method, designated as **RM-26A-1**, for enforcement of the proposed tolerances. This method is essentially the same as that published in PAM II, §180.412, which is used to analyze for sethoxydim residues in plant and animal commodities.

This method has been referred to as the "common moiety" method and it was noted in the review that this method is **not** able to differentiate between residues arising from clethodim (SELECT Herbicide) and structurally similar sethoxydim (POAST Herbicide), which already has established tolerances (40 CFR §180.412) for cottonseed, soybeans and animal products. Dr. Nelson further noted that the "common moiety" method could be used as the primary enforcement method for clethodim residues (assuming it passed an EPA validation trial) and a "compound specific" confirmatory method (which the petitioner claimed to have under development) could be utilized for differentiation between residues arising from clethodim and sethoxydim.

The "common moiety" method was revised by the petitioner and redesignated as **RM-26B-2**. An Agency Petition Method Validation (PMV) was initiated for the "common moiety" method and the results of the PMV were discussed in F.D. Griffith's memo of April 19, 1991. In that memo, CBTS concluded that the "common moiety" method, RM-26B-2, as proposed for enforcement of total clethodim tolerances has had a successful PMV.

Subsequently, the petitioner submitted the clethodim confirmatory method, designated as **RM-26D-1** and referred to as the "compound specific" method. An Agency PMV was initiated for this method. The results of the PMV were discussed in F.D. Griffith's memo of July 30, 1991. In that memo, CBTS concluded that the method as prepared by Valent failed the PMV, but that a modified version of the method may be suitable. A PMV was performed on the modified "compound specific" method and the modifications were forwarded to the petitioner. At that time, CBTS recommended for the establishment of the requested tolerances with an expiration date for the total clethodim residues, **if** the petitioner agreed to rewrite the compound specific method as suggested by the Analytical Chemistry Branch, generate the requested additional validation data, and resubmit this method data package for Agency review, and additional testing or revisions as necessary. CBTS further stated that once there is a compound specific method that has passed an Agency PMV with acceptable independent laboratory validation, then CBTS could recommend for permanent clethodim tolerances.

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To summarize, the "common moiety" method, RM-26B-2, is the primary clethodim enforcement method and it has been successfully validated by the Agency's Analytical Chemistry Branch, but a confirmatory method that distinguishes between clethodim and sethoxydim residues is needed. This confirmatory method or "compound specific" method, RM-26D-1 has been developed, but additional data requirements, as outlined in F.D. Griffith's memo of 7/30/91 are needed prior to Agency acceptance of the method for publication in PAM II.

CBTS suggests that the FR Notice contain the following discussion concerning the analytical methods:

> These tolerances and food additive regulations are being established as tolerances with an expiration date because no independently validated compound specific confirmatory method yet available has passed an Agency petition method validation. A common moiety analytical method for tolerance enforcement (gas chromatography with flame photometric detector in the sulfur mode) was satisfactorily tested and is available. However, this method cannot distinguish between clethodim and sethoxydim, a closely related herbicide with tolerances established under 40 CFR §180.412. A compound specific confirmatory method (HPLC with a UV detector) that can distinguish between derivatives of clethodim and sethoxydim was tested in the Agency laboratory. Considerable revisions were made by the Agency laboratory in order to obtain satisfactory analytical results. The compound specific confirmatory method has been returned to Valent for re-writing and subsequent validation, including validation by an independent laboratory. Valent must submit this information within 1 year from the date of the establishment of these tolerances and food additive regulations.
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> The nature of the residue is adequately understood and a common moiety analytical method (gas chromatography with flame photometric detector in the sulfur mode) is available for enforcement purposes. The independent validation of the compound specific confirmatory method is due within 1 year. Prior to publication in the Pesticide Analytical Manual, Vol. II, the common moiety method ...

We believe the above discussion and the proposed revision of the draft FR Notice will address OGC questions.

cc: WD Wassell, RF, Circ., PP#9F03743/FAP#1H05614, PIB/FOD (Furlow), Clethodim SF

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