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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

AUG 20 1996

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#3F4229/FAP#3H5674. Oxyfluorfen in or on Peanuts. Amendment Dated 7/2/96 in Response to CBTS Review, Revised Sections B and F. DP Barcode: D228055, Chemical No.: 11601, Case No: 284770, CBTS No: 17391, MRID No.: None.

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Health Effects Division (7509C)

Executive Summary of Residue Chemistry Deficiencies

CBTS is recommending for time-limited tolerances for the residues of oxyfluorfen *per se* on the raw agricultural commodities peanut nutmeat and hay at 0.05 ppm. Although additional data are needed for analytical methods for oxyfluorfen *per se*, enforcement methods are available for combined residues of oxyfluorfen and its metabolites. CBTS reiterates that for permanent tolerances, the following deficiencies need to be resolved:

Plant Analytical Method:

Clarification of Performing Laboratory and an ILV.

Animal Analytical Method:

Additional Data for Meat, Milk, Poultry, and Eggs Methods and an ILV.

Magnitude of Residue Data:

Fortification or Bridging Data in Support of Previously Submitted Peanut Residue Data and Clarification of Performing Laboratory.

Plant or Peanut Storage Stability Data.

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Background

Rohm and Haas Company has responded to CBTS review of PP#3F4229/FAP#3H5674, W. Cutchin, 5/10/96 which was a review of data submitted by the petitioner in response to CBTS review of PP#3F4229/FAP#3H5674, DP Barcodes: D192408, D196984, D197110, W. Wassell, 5/12/94. The registrant is seeking permanent tolerances on peanuts and peanut commodities for residues of the herbicide oxyfluorfen [2-chloro-1-(3-ethoxy-4-nitrophenoxy)-4-(trifluoromethyl)benzene] and its metabolites containing the diphenyl ether linkage. The registrant has responded to our last review by submitting revised Sections B and F and now requests oxyfluorfen *per se* tolerances on the raw agricultural commodities peanut nutmeat and hay at 0.05 ppm. The registrant is no longer seeking tolerances on peanut hulls and food/feed additive tolerances peanut meal and refined oil.

Oxyfluorfen is a FIFRA '88 List B pesticide active ingredient and a Phase 4 Review of the chemical has been completed (S. Funk, 03/16/91).

Conclusions

1. The proposed use outlined in Section B is adequate. No further information is necessary for this proposed use.
- 2a. CBTS reiterates that the new plant analytical method for oxyfluorfen *per se* is inadequate but upgradeable. CBTS notes that there is an enforcement method for oxyfluorfen in plants published in PAM Vol. II as Method I which determines levels of oxyfluorfen and its metabolites by a common moiety method. To upgrade the new method, the registrant must clarify what part or parts of the submitted validation study (on soybeans and grapes) and peanut residue trials were undertaken by the two performing laboratories. The registrant must also submit an independent laboratory validation (ILV) of the analytical method.
- 2b. CBTS reiterates that the animal analytical methods for oxyfluorfen *per se* are inadequate but upgradeable. The registrant must submit additional data (including radiovalidation) and a confirmatory procedure for the various methods and an ILV of the methods. Refer to the 11/15/94 and 12/19/95 S. Knizner reviews conducted in conjunction with reregistration for details. CBTS notes that a common moiety method is available in PAM II (Method II) for residues of oxyfluorfen and its metabolites in animal commodities.
3. CBTS reiterates that the magnitude of the residue data for oxyfluorfen on peanuts is inadequate. Since different analytical methods were used in the previous and new field trials, the petitioner must provide bridging data for the residue data previously submitted for peanuts. Alternatively, the petitioner

could provide the additional recovery data requested previously for Method TR# 31C-87-16 (see 5/12/94 review of this petition) or conduct additional field trials using the new method for residues of oxyfluorfen *per se*. The petitioner must also clarify which part or parts of the studies reviewed 5/10/96 were undertaken by the performing laboratories.

4a. As peanut hulls are no longer considered a significant livestock feed, the registrant has removed peanut hulls from Section F.

4b. CBTS reiterates that the registrant has proved, by finding no residues on peanuts treated with oxyfluorfen at an exaggerated rate equal to the concentration factor for peanut processed commodities, quantifiable residues on peanut processed commodities are unlikely. The registrant has provided a revised Section F, deleting the food/feed additive tolerances for peanut oil and meal.

5. CBTS reiterates that the storage stability data for oxyfluorfen on peanuts are inadequate. The registrant has submitted only a summary table of storage stability data. Until the data are received, reviewed, and found acceptable by CBTS, the deficiency remains.

Recommendations

CBTS recommends for time-limited tolerances for the residues of oxyfluorfen *per se* on the raw agricultural commodities peanut nutmeat and hay at 0.05 ppm. CBTS reiterates that in order to make the requested tolerances permanent, the registrant should submit the data requested in 2a, 2b, 3, and 5.

A DRES run may be conducted at this time using the above levels.

Detailed Considerations

Proposed Use

The registrant has submitted a revised Section B. All of the Section B deficiencies pointed out in our original review (PP#3F4229/FAP#3H5674, DP Barcodes: D192408, D196984, D197110, W. Wassell, 5/12/94) had been satisfied except one. The registrant had included in the last sentence of the first paragraph under the "General Information" section wording that implies postemergence applications of the product may be made. The registrant has rewritten the sentence in a revised Section B, "For a full season weed control, timely cultivations and/or a postemergence weed control program, with products approved for the specific crop other than GOAL 1.6E, will assist in weed control." The deficiency has been satisfied.

Analytical Methods - Enforcement and Data CollectionPlants MRID#s 437568-04 (reviewed 5/10/96)

An enforcement method for oxyfluorfen in plants (almonds, corn, grapes, soybeans, and stone fruit) is published in PAM Vol. II as Method I. This method determines levels of oxyfluorfen and its reduced metabolites by a common moiety method as a heptafluorobutyramido derivative of oxyfluorfen. This method was reviewed in conjunction with Phase 4 Review of the chemical and was considered adequate for Phase 5 review (see the oxyfluorfen Phase 4 Review of 3/16/91, S. Funk). However, as tolerances will be established on oxyfluorfen *per se*, this common moiety procedure will not be appropriate for enforcement purposes.

The registrant submitted a new GC/ECD method, TR 34-94-150, which the registrant will rename TR 34-95-111 in 9/95, as the method for the determination of oxyfluorfen *per se* residues on plants. The method was found by CBRS to lack an appropriate confirmatory method and a GC/MS method is under development (DP Barcode: D221731, CBRS#: 16622, S. Knizner, 12/19/95). The registrant included a validation study showing recovery data using this method on soybeans and grapes (MRID# 437568-04, 5/10/96). It is not apparent from the submission which of the performing laboratories, Rohm and Haas Co. and Centre Analytical Laboratories, performed which part or parts of the validation. CBTS reiterates that this must be clarified. In addition, an independent method validation (ILV) must be submitted followed by a tolerance method validation (TMV) in order for the method to be accepted as an adequate enforcement method in accordance with PR 96-1.

The registrant included fortification and recovery data with new peanut residue studies using this method (MRID# 437568-05, 5/10/96). The peanut recovery data summarized by the registrant do not agree with the fortification recoveries presented with the residue trial data by the performing labs, Rohm and Haas Co. and Centre Analytical Laboratories, Inc. The registrant must explain the discrepancy. Also, it is not apparent from the submission which lab performed which part or parts of the procedure. This must still be clarified.

Included in the residue study was a log of method modifications used by the labs. Since this method is intended to be the enforcement for oxyfluorfen on plants, the registrant is again instructed to make the needed revisions to the method and have the method validated by an independent laboratory to satisfy the requirements in PR Notice 96-1 for an ILV. If the ILV is found acceptable by CBTS, the method must undergo a successful tolerance method validation (TMV) by the Agency in order to become an adequate enforcement method.

Animals

The registrant submitted new analytical enforcement methods for oxyfluorfen *per se* in meat, milk and eggs (DP Barcode: 207134, MRID#s: 43307502, 43346401, and 43307503, CBRS#s: 14321 and 14323, S. Knizner, 11/15/94). The submitted analytical enforcement meat/milk/egg methods are not adequate but are upgradeable. The majority of the deficiencies involve clarifications to the method or corrections for Branch policies. The only new data needed are radiovalidation of the method using egg samples from the metabolism study and development of a GC/MS confirmatory method or interference study (DP Barcode: D221731, CBRS#: 16622, S. Knizner, 12/19/95).

The registrant is again reminded that after making the requested modifications, the methods must undergo independent laboratory validation (ILV) followed by Agency TMV as per PR Notice 96-1.

Storage Stability:

The registrant's summary tables indicate that oxyfluorfen residues are stable on plant matrices for up to 3 years. However, no storage stability data on plant matrices have been received to date. CBTS again defers judgement on the acceptability of the studies until such time as plant storage stability data are submitted.

Magnitude of Residue - Crop Field Trials
MRID No.: 437568-05 (5/10/96)

The registrant submitted data from three additional residue trials on peanuts conducted in 1993 and 1994. The registrant used the new method, TR 34-95-111, for data collection. No residues were found on any nutmeat sample <0.02 ppm (LOQ) at any application rate. The shell and hay also exhibited no residues (<LOQ). The only quantifiable residue found was on a vine sample at the LOQ, 0.02 ppm. It is not apparent from the submission which of the performing laboratories, Rohm and Haas Co. and Centre Analytical Laboratories, Inc. performed which part or parts of the procedure. This must still be clarified.

The fortification studies on soybeans and grapes included in the petition (MRID# 437568-04, 5/10/96) indicate the proposed new method should be adequate for data collection from plant matrices. However, fortification data submitted for a new method will not support data from a previous method. Therefore, the additional recovery data requested for Method TR# 31C-87-16 in our 5/12/94 review are still needed. Alternatively, the registrant may provide bridging data showing that the new method and old method generate similar results from actual residue samples. The registrant is advised to use samples from one of the recent residue studies or to generate new residue samples for simultaneous analysis with the two

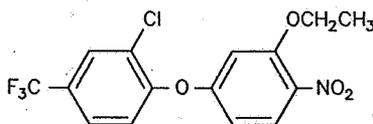
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methods. Should the results be comparable, CBTS could consider the previously submitted residue data in support of the proposed tolerance. In lieu of bridging data or additional recovery data, the registrant may replace the data in question. The registrant will need six additional trials to replace those trials in question, if no residues are quantifiable.

Magnitude of Residue - Processed Products

The registrant submitted data showing no residues on peanut nutmeats following a 3x exaggerated application to peanuts. Therefore, no tolerances are required for peanut processed commodities for the proposed use. The registrant has submitted a revised Section F requesting the tolerances on peanut nutmeat and peanut hay at 0.05 ppm. Food/feed additive tolerances on peanut oil and meal have been deleted.

OXYFLUORFEN



cc: Cutchin, RF, Circ., PP#3F4229/3H5674, Oxyfluorfen List B Reregistration file, B. Sidwell (SRRD, 7508W), SAB (E. Doyle), J. Miller/E. Wilson - PM-23 (7505C).

7509C: CBTS, Reviewer (WDC), CM#2, Rm 804P, 305-7990, WDC: 8/19/96
RDI: Br. Sr. Sci.: R. Loranger: 8/9/96;
Act. Br. Ch.: E. Haeberer: 8/12/96.