



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

EXPEDITE

MAR 18 1992

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM:

SUBJECT: PP#9G3817/2H5628. Expedited Review Request for EUP and Temporary Tolerance for Tebuconazole/Folicur in/on Peanuts (EPA Reg. No. 3125-EUP-ENN) Dated January 29 and March 4, 1992. CBTS Nos. 9383, 9384, and 9385. DP BARCODE D173742. MRID No. 421558-01.

FROM: Gary F. Otakie, P.E., Chemist
Tolerance Petition Section II
Chemistry Branch I - Tolerance Support
Health Effects Division (H7509C)

THRU: Debra F. Edwards, Acting Chief
Chemistry Branch I - Tolerance Support
Health Effects Division

*Q**

$$Q^* \times TMRC = \text{conc. risk}$$

1

$$Q^* \times \frac{0.000009571}{0.00001} = 10^{-6}$$

mg/kg BWT/day

$$\text{reference } Q^* = \frac{10^{-6}}{10^{-5}}$$

$$Q^* = .104$$

Q that we come up with would have to be 0.1 (mg/kg/day) -
or less unless the conc risk from peanuts would exceed 10⁻⁶
(assuming 70 lb person)*

- Per a December 9, 1991 review of CBRS recommended against approving prop for tebuconazole on grapes or peanuts b deficiencies including questions on the for which the petitioner has provided a submission under MRID No. 421558-01.

- Per a March 6, 1992 review of PP#9G3817 by B. Cropp-Kohliligian in response to deficiencies iterated in the above



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463T
New chem,
no DRES file
has an RFD; see PROUDOC note.

J. HARRIS (URES)
received 3-18-92
NOVA SPK
no advance notice.

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Chemistry Branch I - Tolerance Support
Health Effects Division (H7509C) *Gary F. Otakie*

THRU: Debra F. Edwards, Acting Chief
Chemistry Branch I - Tolerance Support
Health Effects Division (H7509C) *Debra Edwards*

TO: Susan T. Lewis/Julie Fairfax PM 21
Fungicide - Herbicide Branch
Registration Division (H7505C)

Note: This review is being expedited at the request of A. Lindsay, per a March 2, 1992 memo to P. Fenner-Crisp. The expedited review is requested by March 18, 1992 since the decision on the EUP and temporary tolerances needs to be made prior to this use season so that data can be gathered to support the petitioners pending application for permanent tolerances and registration. Additionally, the Peanut Council has expressed great interest in this use pattern.

Background

- Per a December 9, 1991 review of PP#9G3817 by S. Hummel, CBRS recommended against approving proposed temporary tolerances for tebuconazole on grapes or peanuts because of several deficiencies including questions on the poultry metabolism study for which the petitioner has provided a response in this submission under MRID No. 421558-01.

- Per a March 6, 1992 review of PP#9G3817 by B. Cropp-Kohlligian in response to deficiencies iterated in the above



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referenced 12/9/91 review, CBRS recommended in favor of the proposed peanut EUP and associated tolerances provided four remaining deficiencies were resolved (see Detailed Considerations). The petitioner revised PP#9G3817 by deleting the temporary tolerance requests for all grape commodities without prejudice to a future filing. Further issues relating to tolerances in animal commodities became moot for purposes of the subject temporary tolerance request for peanuts, since the draft label dated 10/1/91 included a restriction against feeding treated peanut hay/vines to livestock.

- A permanent tolerance for tebuconazole on peanuts is proposed under PP# 9F3724 and 9H5575.

Conclusions

1. All deficiencies iterated in CBRS's 3/6/92 review have been resolved with the exception of aerial application.

2. CBTS does not object to the proposed use of aerial application in select locations under the subject EUP provided the label is revised to include aerial application and that the proposed spray volume per acre be specified and that EEB and EFB do not object. The petitioner should note that under current EPA policy aerial applications using spray volumes of less than 2 gallon per acre cannot be supported by only ground application data.

3. Further issues relating to tolerances in animal commodities are irrelevant for purposes of the subject temporary tolerance request for peanuts, since the draft label dated 10/1/91 included a restriction against feeding treated peanut hay/vines to livestock. The data included in the current submission in response to questions concerning the poultry metabolism study (i.e. MRID No. 421558-01) has been moved to and will be reviewed under the permanent petition file # 9F03724 for tebuconazole on peanuts.

Recommendation

CBRS recommends in favor of the proposed EUP and temporary tolerances for the new chemical tebuconazole on peanuts TOX, EFGB and EEB considerations permitting, provided that, if aerial application is to be included in the EUP, the proposed label is revised to include aerial application and a recommended minimum spray volume of at least 2 gallons per acre specified.

Present Submission

1. Revised Tolerance Proposal Including Food/Feed Additive Petition # 2H5628 for Peanut Oil and Peanut Soapstock

Section F

Temporary tolerances are proposed for residues of the fungicide tebuconazole (Alpha-[2-(4-Chlorophenyl)ethyl]-Alpha-(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol) in or on the following commodities.

<u>Commodity</u>	<u>PHI (Days)</u>	<u>Proposed Tolerance (ppm)</u>
Peanuts	14	0.1
Peanut Hulls	14	4.0

Food Additive Proposal

Peanut Oil	0.5
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Feed Additive Proposal

Peanut Soapstock	0.5
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2. Revised Section G

Per a 3/4/92 letter from John S. Thornton of Miles Inc. a revised form 8570-17 and Section G were revised as follows:

A. The proposed period of shipment/use has been changed to May 1, 1992 to December 31, 1992.

B. Since the current proposed EUP label, dated 10/1/91, calls for 4 applications per season rather than 7 applications, less product is needed for the EUP. Therefore, the total quantity proposed for shipment/use has been reduced from 207.8 gallons (748.1 pounds a.i.) to 118.8 gallons (425.5 pounds active ingredient).

C. Section G has been revised to reflect changes in the Miles personnel which will supervise the EUP. A copy of the revised G is included as Attachment 1.

3. New Data

The petitioner has submitted new data concerning questions raised in CBRS's 12/9/92 review of poultry metabolism (i.e. MRID No. 421558-01).

Detailed Considerations

The deficiencies listed in CBRS's March 6, 1992 review are reiterated below followed by the Petitioners Responses and CBTS's Comments/Conclusions.

Deficiency No. 1

The registrant must submit a revised Section F (as drafted 9/26/91) of PP#9G3817 deleting the proposed temporary tolerance for tebuconazole residues in/on peanut hay.

Petitioner's Response to Deficiency No. 1

The petitioner has submitted a revised Section F dated 3/4/92 deleting the proposed tolerance on peanut hay.

CBTS's Comments/Conclusions re: Deficiency No 1

This deficiency is resolved.

Deficiency No. 2

The registrant must establish an H petition for the temporary food/feed additive tolerances. Also, the registrant must further revise the Section F (dated 9/26/91) specifying a Food Additive Tolerance in Peanut Oil (delete reference to "crude or refined") at 0.5 ppm and a Feed Additive Tolerance in Peanut Soapstock at 0.5 ppm for the parent compound, tebuconazole, only.

Petitioner's Response to Deficiency No. 2

An H petition and a revised Section F deleting reference to crude or refined peanut oil and proposing food/feed additive tolerances for the parent only at 0.5 ppm in peanut oil and peanut soapstock has been submitted.

CBTS's Comments/Conclusions re: Deficiency No. 2

This deficiency has been resolved.

Deficiency No. 3

The registrant needs to specify the duration of the EUP for use of Folicur 3.6 F on peanuts (3125-EUP-ENN) so the expiration of the proposed temporary tolerances for peanut commodities can be established. The time frame specified in the original application for the EUP was from May 1 through December 31 of 1990.

Petitioner's Response to Deficiency No. 3

The proposed period of shipment/use has been changed to May 1, 1992 to December, 31 1992.

CBTS's Comments/Conclusions re: Deficiency No. 3

This deficiency has been resolved.

Deficiency No. 4

The registrant should be aware that aerial applications have not been approved for the use of Folicur 3.6 F on peanuts since they are not included in the EUP label (draft dated 10/1/91) although aerial applications were specified in the original EUP application (3125-EUP-ENN). The registrant should make clear their intent concerning aerial applications.

The registrant should reference the existing aerial field trial data (MIRD No. 417174-09) in their next submission for the copending permanent tolerance petitions.

Petitioner's Response to Deficiency No. 4

The petitioner has not responded directly to this deficiency. However, we note that their latest submission dated 3/4/92 proceeds the date of the CBRS 3/6/92 review discussing this deficiency.

CBTS's Comments/Conclusions re: Deficiency No. 4

We note that the revised Section G in this submission and included as Attachment 1 to this review does state "some aerial applications will be made in selected trial locations." Further we note that the latest draft label dated 10/1/91 does not provide for aerial application.

A CBTS/CBRS policy memo-Requirement for Crop Field Trials to Support Aerial Applications dated 12/6/91 granted a waiver for residue data supporting aerial applications provided adequate ground data are available and that the label specify a minimum spray volume of 2 gallons (i.e water as diluent) per acre.

Under the circumstances CBTS does not object to the proposed use of aerial application in select locations under the subject EUP provided the label is revised to include aerial application and that the proposed spray volume per acre be specified and that EEB and EFB do not object. The petitioner should note that under current EPA policy aerial application using spray volumes of less than 2 gallons per acre cannot be supported by only ground application data.

Attachment 1 - Revised Section G Dated 3/4/92

cc: Reviewer-Otakie, C. Furlow (PIB/FOD), RF, Circu, PP#9G3817, PP#9F03724, B. Cropp-Kohlligian (CBRS), E. Haeberer, J. KARIYA (DRES)
RDI: EHaeberer: 3/17/92 RLoranger: 3/17/92