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

25 OCT 1988

EXPEDITE

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: PP#7F3476/FAP#7H5524. Myclobutanil (RALLY) in or on
Apples, Grapes, Their Byproducts, Meat, Milk, and Eggs.

Amendment of 10/7/88.

DEB Nos.: 4508-4509.
MRID No.: N/A.
HED Project #: 9-0172.

FROM: Maxie Jo Nelson, Ph.D., Chemist
Dietary Exposure Branch
Health Effects Division (TS-769C)

THRU: Charles L. Trichilo, Ph.D., Chief
Dietary Exposure Branch
Health Effects Division (TS-769C)

TO: Lois Rossi, PM #21
Fungicide-Herbicide Branch
Registration Division (TS-767C)

Toxicology Branch - HFA Support
Health Effects Division (TS-769C)

Science Analysis & Coordination Branch
Health Effects Division (TS-769C)

This review is being EXPEDITED at the request of the Registra-
tion Division (9/28/88 memo of E. F. Tinsworth, Acting Director).
The due date for its completion is 10/31/88.

Myclobutanil is a new chemical, and this petition is proposing
the first food-use permanent tolerances.

DEB's initial review of this petition (dated 2/8/88) was format-
ted to serve as a Registration Standard (RS) for Myclobutanil.
For the sake of expediency, the amendment reviews have not been
in the RS format.

Once the remaining deficiencies have been resolved, a revised
version of the residue chemistry "chapter" of the Registration
Standard for Myclobutanil will be prepared. That document will
be accompanied by a Table A (Generic Data Requirements).

pmsp/ISB

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SUMMARY OF DEFICIENCIES REMAINING TO BE RESOLVED FOR DEB

- The PMV for RH-9090 (bound)/milk must be evaluated by DEB, and the method accepted by DEB as suitable for regulatory purposes.
- A final decision on the adequacy of the proposed tolerance level for milk is deferred until the results of the PMV for RH-9090 (bound)/milk are evaluated.

CONCLUSIONS

- 1a. A revised Section F has been submitted with a corrected tolerance level (0.3 ppm) proposed for liver.

The other revisions we requested in our 10/13/88 review (M. Nelson) are not incorporated into this Section F (due to the timing of its submission).

Those revisions, listed below, will be handled by the PM on an administrative basis when the FR notice for the establishment of tolerances is prepared:

- o Replace reference to 21 CFR 193 with 40 CFR 185;
- o Replace reference to 21 CFR 561 with 40 CFR 186; and,
- o Specify the pomace proposals in terms of "Apple pomace (wet and dry)" and "Grape pomace (wet and dry)".

We consider this deficiency to be adequately resolved.

- > 1b. Final judgment on the adequacy of the proposed tolerance level of 0.05 ppm for milk is deferred pending review of the PMV results for RH-9090 (bound) in milk.
- > 2. Judgment on the adequacy of the RH-9090 (bound)/milk method for generating residue data and for enforcing the proposed tolerance on milk is deferred, pending evaluation of the PMV report.
- 3. At such time as DEB is able to make a favorable recommendation for the establishment of the tolerances proposed by this petition, a copy of that DEB review will be routed to SAOS/SACB/HED for their use in preparing any TAS assessment which may be required.
- 4. An updated International Residue Limits (IRL) Status sheet will be appended to the DEB review which is able to recommend favorably for the establishment of the pending proposed tolerances.

RECOMMENDATION

DEB defers a favorable recommendation for the establishment of the proposed tolerances of this petition, pending satisfactory resolution of the issues pending in Conclusions 1b and 2.

No further action is required of the petitioner at this time.

*** NOTE TO PM ***

The complete report of the BEAD petition method validation (PMV) of the RH-9090 (bound)/milk analytical method has just been received in DEB (10/25/88).

As indicated in the HED memorandum of 10/3/88 (T. M. Farber, Ph.D., Director, HED, to E. F. Tinsworth, Acting Director, RD), DEB is committed to completing its review of this PMV report on an expedited basis within 2 weeks of receipt. The due date for completion is thus 11/8/88.

Once DEB's evaluation report of the PMV issues, DEB will write a follow-up review for this petition clarifying what/if deficiencies remain outstanding based on the PMV findings, and what action, if any, may then be required on the petitioner's part in furtherance of their tolerance requests.

PM, please also note our comment under Conclusion 3.

DETAILED CONSIDERATIONS

INTRODUCTION

By transmittal letter dated 10/7/88, the petitioner (Rohm and Haas Company (RH)) has submitted a revised Section F to this petition.

REVISED SECTION F

The petitioner's latest Section F corrects the typo (0.03 ppm) in the tolerance level proposal for liver, which is now correctly proposed at 0.3 ppm.

In our (M. Nelson) review of 10/13/88, we raised the need for such a correction as one of the deficiencies remaining to be resolved for this petition. We consider the petitioner's submission (received in DEB on 10/18/88) to adequately resolve that deficiency.

We note that DEB had requested other (administrative) changes be incorporated into the revised Section F which the petitioner was to submit.

Those have not been made since the petitioner submitted this corrected Section F prior to receiving our review detailing all the changes we wished incorporated.

DEB has discussed this with the PM, and it has been determined the other revisions can be handled administratively by the PM at the time of issuing the FR notice for the establishment of tolerances.

The revisions to be administratively incorporated by the PM are:

- Replace reference to 21 CFR 193 with 40 CFR 185;
- Replace reference to 21 CFR 561 with 40 CFR 186;
and,
- Specify the pomace proposals in terms of "Apple pomace (wet and dry)" and "Grape pomace (wet and dry)".

ANALYTICAL METHOD FOR BOUND RH-9090 IN MILK

The complete report of the BEAD petition method validation (PMV) of the RH-9090 (bound)/milk analytical method has just been received in DEB (10/25/88).

As indicated in the HED memorandum of 10/3/88 (T. M. Farber, Ph.D., Director, HED, to E. F. Tinsworth, Acting Director, RD), DEB is committed to completing its review of this PMV report on an expedited basis within 2 weeks of receipt. The due date for completion is thus 11/8/88.

Pending completion of DEB's evaluation of this PMV, the following two deficiencies (from our M. Nelson 10/13/88 review) re this petition remain unresolved:

- Final judgment on the adequacy of the proposed tolerance level of 0.05 ppm for milk is deferred pending review of the PMV results for RH-9090 (bound) in milk.
- Judgment on the adequacy of the RH-9090 (bound)/milk method for generating residue data and for enforcing the proposed tolerance on milk is deferred, pending evaluation of the PMV report.

OTHER CONSIDERATIONS

Tolerance Assessment System (TAS) Evaluation: TAS considerations are now under the purview of the Special Analysis & Outreach Section (SAOS) of the Science Analysis and Coordination Branch (SACB), HED.

At such time as DEB is able to make a favorable recommendation for the establishment of the tolerances proposed by this petition, a copy of that DEB review will be routed to SAOS/SACB/HED for their use in preparing any TAS assessment which may be required.

International Harmonization: An updated International Residue Limits (IRL) Status sheet will be appended to the DEB review which is able to recommend favorably for the establishment of the pending proposed tolerances.

cc: M. Nelson
PP#7F3476/FAP#7H5524
Myclobutanil Registration Standard File
Reading File
Circulation (7)
ISB/PMSD (Eldredge)

TS-769C:DEB:Reviewer(MJN):CM#2:Rm804:557-7324:typist(mjn):10/25/88.

RDI:SectionHead:RSQuick:10/25/88:DeputyChief:RDSchmitt:10/25/88.