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

DEC 19 1986
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EXPEDITE

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA File No. 46193-O. Additional product chemistry data for new trifluralin technical (Retzloff Delta). (No Accession Number) [RCB# 1750]

FROM: Richard Loranger, Chemist *R. Loranger*
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

THRU: Charles L. Trichilo, Chief
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

TO: Richard Mountfort, PM 23, HFB
Registration Division (TS-767)

This review is being expedited per the request of Edwin F. Tinsworth, Director, Registration Division (12/15/86 memo to John W. Melone, Director, HED).

Our recent review of data concerning Retzloff Delta Company's technical trifluralin had questions on the levels/certified limits of impurities (Deficiency 3) and on the quality control method for nitrosamines (Deficiency 8) (12/4/86 R. Loranger memo). Each of these deficiencies is discussed below along with the applicant's latest response and our final conclusion.

Deficiency 3

Questions still remain about the levels of impurities present at $>0.1\%$ in the technical trifluralin and their certified limits. A summary should be prepared listing the impurity levels in the original five batches, the four batches in the August submission, the two additional batches noted in the present package, and in any other relevant analyses of which the applicant is aware. From this summary appropriate certified limits should be proposed.

Retzloff Delta response:

A total of 13 batches of the technical have been analyzed—five in the original package, four in the August response to RCB's 6/19/86 review, plus four more which were "screened" 7/23/86 in response to that same review. The complete "validation" of these four batches took place in response to RCB's 10/9/86 review. A summary table of all the analyses and certified limits is provided.

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RCB's Comments/Conclusion on Deficiency 3:

A copy of the summary table on impurity and active ingredient levels is in the Confidential Appendix to this review. Our detailed discussion on these levels also appears in the Appendix. In summary, the change in the certified limit of one impurity has now been satisfactorily explained. We are able to verify the calculations of impurity levels in the four batches (00385, 01085, 04385, 06285) [REDACTED] in

the current submission. The certified limits in the table are acceptable. We note that the proposed limit for active ingredient

[REDACTED] Either number is acceptable based on the 13 batch analyses. We have been informed that the value in the CSF should be taken as the official limit [REDACTED]

We conclude that this deficiency has been resolved. A sufficient number of batches have been analyzed and acceptable certified limits provided in the 8/19/86 CSF.

Deficiency 8

The applicant has not firmly demonstrated that the analytical method in their quality control procedure determines nitrosamines in the presence of technical trifluralin. Data must be provided to show what [REDACTED]

Retzloff Delta response:

"Our methods have been confirmed in the past by running split samples concurrently with Thermedics. Comparative results of the two methods are consistent. The reviewer has accepted the Thermedics method as being valid for enforcement purposes." We believe the request for 0.1 ppm spikes is too low. Thermedics methods are validated at ca 0.5 ppm and this is the range we expect to validate. However, we will attempt to generate recoveries at the 0.1 ppm level.

RCB's Comments/Conclusion on Deficiency 8:

[REDACTED]

We reiterate that such a procedure is satisfactory on a temporary basis. However, the applicant must still

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submit recovery data for their in-house method to show they can determine total nitrosamine content [REDACTED]

[REDACTED] data at the requested 0.1 ppm spiking levels should be coming to the Agency within the next few weeks (phone call 12/18/86).

CONCLUSIONS AND RECOMMENDATION

1. A sufficient number of analyses have been conducted for the active ingredient and impurities in the technical trifluralin produced by [REDACTED]. The certified limits on the Confidential Statement of Formula dated 8/19/86 are acceptable.

[REDACTED] However, within 90 days of approval of this registration the recovery data requested for [REDACTED] in-house analytical method for nitrosamines must be submitted. These data should show that the producer can measure down to about 0.1 ppm [REDACTED]

technical trifluralin.

Provided the applicant institutes the interim quality control procedure described in Conclusion 2 and promises to develop the validation data for the in-house nitrosamine method, we have no objections to this registration.

* Attachment-Confidential Appendix (Copies to PM-23, Trifluralin SF, Reading file, Loranger, PMSD/ISB)

cc: Circu, RF, Trifluralin SF, Loranger, PMSD/ISB
RDI:Section Head:ARRathman:12/19/86:RDSchmitt:12/19/86
TS-769:RCB:R.Loranger:557-7324:RAL(9):CM#2:RM.804:Date:12/19/86

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