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

DEC 4 1986

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# 1661]

FROM: Richard Loranger, Chemist
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THRU: Charles L. Trichilo, Chief
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TO: Richard Mountfort, PM 23, HFB
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In response to our 10/9/86 review the Retzloff Delta Company has submitted additional product chemistry data for their technical trifluralin (active ingredient a,a,a-trifluoro-2,6-dinitro-N,N-di-n-propyl-p-toluidine). The information requested in our previous memo included an explanation of nitrosamine calculations and recovery data for [redacted] (Conclusion 2), an explanation of a change in one certified limit (Conc. 3), data on explodability (Conc. 5), and a description plus recovery data for the nitrosamine quality control procedure (Conc. 8). The applicant's response to each of these will be discussed below followed by our conclusion.

Deficiency 2

Various explanations of the nitrosamine analyses/calculations are requested along with recovery data for either [redacted]

Retzloff Delta's response:

[redacted]

[redacted]

RCB Comments/Conclusion on Deficiency 2:

An adequate explanation of the calculation of nitrosamine levels has been provided.

[redacted]

Since this is below the 0.5 ppm ceiling for technical trifluralin, additional analyses will not be required. This deficiency has been resolved. However, we note that some questions still remain concerning the applicant's in-house quality control procedure (see deficiency 8).

Deficiency 3

New certified limits reflecting additional batch analyses are satisfactory with the exception of one impurity whose limit was increased substantially even though lower concentrations were observed in the four additional batches. The applicant must explain why this limit was so revised.

Retzloff Delta response:

In the additional analyses requested by EPA (6/19/86 memo) higher levels of this impurity were observed in two batches (see Confidential Appendix of this review for details). The certified limit was modified to account for this increase.

RCB Comments/Conclusion on Deficiency 3:

[redacted] All impurities present at ≥0.1% must be identified and quantified. 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. This deficiency has not been resolved.

Deficiency 5

Acceptable information has been provided for all physical/chemical properties with the exception of explodability (63-16). [redacted] Therefore, this test is required.

Retzloff Delta response:

Impact sensitivity testing was conducted by DustTech Inc. (report dated 10/31/86). A 2 kg weight was dropped from various heights up to 36" onto a carefully designed holder containing the sample. In this test a positive response or initiation is identified by a loud noise, flame, or other evidence of combustion. In ten replicate trials from the maximum 36" height lot AN60030 of technical trifluralin failed to initiate. This can be compared to a 50% initiation frequency for nitroglycerin at a height of 0.39".

RCB Comments/Conclusion on Deficiency 5:

Satisfactory information has been submitted on the explodability of technical trifluralin. This product is not sensitive to impact.

Deficiency 8

[redacted] the trifluralin technical is checked for nitrosamines using [redacted] to ensure they are below 0.5 ppm. To show us that this analytical method is valid for quality control purposes (required by Trifluralin PD 4)

[redacted] provide a detailed description of the procedure as well as typical chromatograms and recovery data (analyses of spiked samples).

Retzloff Delta response:

A description of the analytical method for volatile nitrosamines in triluralin is provided along with a "recovery study". These are discussed in the Confidential Appendix to this review along with RCB comments. [redacted]

RCB Comments/Conclusion on Deficiency 8:

The applicant has not firmly demonstrated that the analytical method determines the nitrosamines in the presence of technical trifluralin. Data must be provided to show what recoveries are obtained when 0.1 ppm [redacted] spiked into technical trifluralin. This deficiency has not been resolved.

SUMMARY OF CONCLUSIONS AND RECOMMENDATION

1. The applicant has supplied adequate nitrosamine data for the technical trifluralin with the maximum content of these impurties below the 0.5 ppm ceiling.

2. Questions still remain about the levels of impurities present at ≥0.1% in the technical trifluralin and their certified limits. See our "Comments/Conclusion on Deficiency 3" (page 3) for details on the additional information required.

3. Satisfactory information has been provided on the explodability of technical trifluralin. This product is not sensitive to impact.

4. The applicant has not firmly demonstrated that the analytical method employed as part of their quality control procedure determines nitrosamines in the presence of technical trifluralin. Data must be provided to show what recoveries are obtained when 0.1 ppm [redacted] technical trifluralin.

We recommend against registration of this trifluralin technical until the data requested in Conclusions 2 and 4 are submitted.

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

cc: Circu, RF, Trifluralin SF, Loranger, PMSD/ISB
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