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

FIDELITY

NOV 24 1993

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#1F4025. MAT 7484 in/on Corn Commodities.
Review of Amendment of 10/1/93.

DPCode: D196062 CBTS: 12727
Chem: 129086 MRID: 429590-00, -01, -02

FROM: Maxie Jo Nelson, Ph.D., Chemist
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Health Effects Division (7509C)

THRU: Robert S. Quick, Section Head
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Health Effects Division (7509C)

TO: M. Mautz/R. Forrest, PM Team 14
Insecticide-Rodenticide Branch
Registration Division (7505C)

and

Albin Kocialski, Section Head
Chemical Coordination Branch
Health Effects Division (7509C)

BACKGROUND

In its product chemistry review of 7/30/93 (M. Nelson) of this subject petition, CBTS cited three deficiencies to be resolved before it could recommend for the requested permanent tolerances for MAT 7484 (rimsulfuron) in/on corn commodities.

This present amendment consists of a transmittal letter (dated 10/1/93) from the petitioner (Miles, Inc.) and two volumes of supplementary product chemistry information (assigned EPA MRID Nos. 429590-01, -02).



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DISCUSSION

The three outstanding deficiencies are restated below, for convenience, followed by the petitioner's response, and our comments/conclusions.

- #1. The information provided in MRID 428088-02 (Miles Brochure No. 1828) for Guidelines Ref. No. (GRN) 63-6 (boiling point) is incomplete in that it does not specify whether TGAI or PAI of MAT 7484 was the test substance; clarification is needed. If TGAI was not used, this study must be redone.

Miles: MAT 7484 does not boil at atmospheric pressure, but decomposes. The previously submitted data for GRN 63-6 used a reference standard which had a purity of 99.6%. To meet EPA's requirements, a new study was conducted with technical grade MAT 7484 (97.2% ai). The initial temperature of decomposition for the TGAI was determined by differential scanning calorimetry to be 105° C.

CBTS: This deficiency is resolved. The new study is designated Mobay Report No. 10262, "Thermal Stability and pH Measurement of BAY MAT 7484: Supplement to EPA MRID 428088-02 Product Chemistry of BAY MAT 7484 Technical", M. Johnson, 9/20/93, located in EPA MRID 429590-02. Miles, Inc. was the performing lab.

- #2. The information provided in MRID 428088-02 (Miles Brochure No. 1828) for 63-12 (pH) is incomplete as the temperature at which the determination was performed is not provided. Also, there is no explanation as to why an acetone:water mixture was used.

Miles: The acetone:water solution was used to ensure solubility of trace organic compounds which may build up on the electrode of the pH meter. To meet EPA's requirements, the pH measurement of BAY MAT 7484 Technical (97.2% ai) was repeated in distilled water only, and was determined to to 6.9 at 20° C.

CBTS: This deficiency is resolved. The new study is designated Mobay Report No. 10262, "Thermal Stability and pH Measurement of BAY MAT 7484: Supplement to EPA MRID 428088-02 Product Chemistry of BAY MAT 7484 Technical", M. Johnson, 9/20/93, located in EPA MRID 429590-02. Miles, Inc. was the performing lab.

- #3. Miles has not yet responded to our request to explain certain aspects of the manufacturing process (GRN 61-2). What we wish clarified is detailed in the Confidential Appendix, attached.

Miles: We are submitting Mobay Report ANR-00793 ("GRN 61-2(a) - Manufacturing Process Description: Supplement to MRID 428088-01 Product Chemistry of BAY MAT 7484 Technical", by L. Fontaine, 9/20/93, assigned EPA MRID No. 429590-01) to respond to this deficiency. The information contained therein is CBI.

CBTS: This deficiency is resolved. For a discussion of the information provided, see the Confidential Appendix to this review.

CONCLUSIONS

1. The information provided in MRID 429590-02 (Miles Report 106262) for GRN 63-6 (boiling point) is acceptable. This deficiency is resolved.
2. The information provided in MRID 429590-02 (Miles Report 106262) for GRN 63-12 (pH) is acceptable. This deficiency is resolved.
3. The information provided in MRID 429590-01 (Miles Report ANR-00793) for GRN 61-2(a) (description of the manufacturing process) is acceptable. This deficiency is resolved.
4. There now remain no outstanding deficiencies to be resolved for CBTS in re this petition.
5. Registration of the formulation (AZTEC 2.1G) and determination as to whether its inert ingredients are cleared is under the purview of RD.
6. A DRES run was requested in conjunction with the temporary tolerance petition (review of 5/18/93, M. Nelson, PP# 2G4048). An additional run at this time is not needed.

RECOMMENDATION

Toxicological considerations permitting, CBTS recommends in favor of the establishment of the permanent tolerances being proposed by the petitioner for residues of phostebupirim (MAT 7484) in/on:

| | |
|--|----------|
| Corn, fresh, includes sweet.....@ | 0.01 ppm |
| Corn, grain, field and pop.....@ | 0.01 ppm |
| Corn, forage and fodder, field, pop, and sweet...@ | 0.01 ppm |

NOTES TO PM:

- (1) Note Conclusions 5 and 6.
- (2) The Agency's tolerance-granting decision for PP# 1F4025 must be consistent with, and synchronized with, that for co-pending cyfluthrin (PP# 1F4026; see CBTS review of 3/9/93, M. Nelson) as both cyfluthrin and MAT 7484 are active ingredients in the AZTEC 2.1G formulation.
- (3) CBTS recommends the proposed tolerance for fresh corn be expressed as "corn, sweet (K + CWHR)" in 40 CFR.

ATTACHMENT: Confidential Appendix - 1 page.

cc (WITH Confidential Appendix): M. Nelson, RF, PP#1F4025.
cc (without Confidential Appendix): Circ., FDA.

7509C:CBTS:MJN:mjn:CM#2:804:305-7324:4025MAT.PC3:11/24/93.
RDI:SecHd&ActgBrChf:RSQuick:11/24/93.

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Page 5 is not included in this copy.

Pages _____ through _____ are not included.

The material not included contains the following type of information:

- Identity of product inert ingredients.
 - Identity of product impurities.
 - Description of the product manufacturing process.
 - Description of quality control procedures.
 - Identity of the source of product ingredients.
 - Sales or other commercial/financial information.
 - A draft product label.
 - The product confidential statement of formula.
 - Information about a pending registration action.
 - FIFRA registration data.
 - The document is a duplicate of page(s) _____.
 - The document is not responsive to the request.
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The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.
