



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

JUL 30 1993

PC 129084
R.F.
CONFIDENTIAL

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#1F4025. MAT 7484 in/on Corn Commodities.
Review of Amendment of 6/9/93.

DPCode: **D192280** CBTS: **12026**
Chem: **129086** MRID: **428088-00, -01, -02**

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THRU: Robert S. Quick, Section Head
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TO: M. Mautz/R. Forrest, PM Team 14
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and

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BACKGROUND

In its initial product chemistry (8/10/92, M. Nelson) and residue chemistry (4/5/93, M. Nelson) reviews of this subject petition, CBTS cited four deficiencies to be resolved before it could recommend for the requested **permanent** tolerances in/on corn commodities.

Two of those deficiencies were subsequently resolved (5/18/93 review, M. Nelson, PP#2G4048), and the remaining two are addressed by this present amendment.

This amendment consists of a transmittal letter (dated 6/9/93) from the petitioner (Miles, Inc.) and two volumes of supplementary product chemistry information (assigned EPA MRID Nos. 428088-01, -02).



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DISCUSSION

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

- #1. *Miles must provide additional data concerning boiling point, density, and pH (Guideline Ref. Nos. (GRN) 63-6, 63-7, and 63-12), as required by 40 CFR §158.190. The temperature of decomposition must be specified in lieu of boiling point. Miles must submit the density and pH data using the TGAI (technical grade, active ingredient) rather than the PAI (pure active ingredient) and perform the determinations at 20 or 25°C.*

Miles: The requested information has been compiled and is submitted as "Supplement to MRID 420054-03, Product Chemistry of MAT 7484 Technical", EPA Guideline Nos. 63-6, 63-7, and 63-12, Miles Inc. Brochure No. 1828, L. D. Fontaine, 5/18/93, 13 pp..

63-6 (Boiling Point). BAY MAT 7484 does not boil at atmospheric pressure, but decomposes. The initial decomposition temperature is 90°C. This information was borne out in the previous submission (MRID 420054-03; Miles Rpt 99182) by the data submitted for the thermal stability determined by TGAI.

In addition, the boiling point was determined at reduced pressure, and at 2 mbar was 133-138°C.

63-7 (Density). The density of BAY MAT 7484 technical was measured according to Miles Test Method A-5.15, and was determined to be 1.0943 g/ml @ 20°C.

63-12 (pH). The pH of a 5% solution of BAY MAT 7484 technical in a mixture of water and acetone was determined to be 5.0, according to Miles Method A-8.1.

CBTS: This volume of data has been assigned EPA MRID No. 428088-02. Miles Inc. was the performing laboratory. CBTS has the following comments on these supplemental data:

(1) The information provided above for 63-6 is incomplete in that it does not specify whether TGAI or PAI of MAT 7484 was the test substance; clarification is needed. (Note: If TGAI was not used, this study must be redone; see Product Chemistry Guidelines, GRN 63-6.) This deficiency is not yet resolved.

(2) The information provided for 63-7 is acceptable. This deficiency is resolved.

(3) The information provided above for 63-12 is incomplete in that the temperature at which the determination was performed is not provided. Also, no explanation as to why an acetone:water mixture was used was given. (Note: If acceptable information can not be provided, this study must be redone. The Product Chemistry Guidelines (GRN 63-12) specifically state: "Each substance for which a pH determination is required shall be diluted or dispersed with **distilled water**. The determination shall be made at 20°C or 25°C...." This deficiency is not resolved.

#2. *Re GRN 61-2 (Beginning Materials and Manufacturing Process), Miles must provide information on the beginning materials, including the names and addresses of the manufacturer/producer/supplier, the brand name/trade name/commercial designation and copies of complete technical specifications/data sheets, a complete list of equipment used, equipment descriptions, and a description of measures taken to assure quality of the final product. Information must also be provided to clarify the description of the manufacturing process; refer to the Confidential Appendix for details of the process deficiencies.*

Miles: Raw material specifications, description of equipment, and quality control measures were previously submitted (MRID 420054-01). Material safety data sheets (MSDS) and the names and addresses of the suppliers of the raw materials used in the manufacture of MAT 7484 technical have been compiled and are submitted as "Supplement to MRID 420054-01, Product Chemistry of MAT 7484 Technical", EPA Guideline No. 61-2, Miles Inc. Brochure No. 1827, L. D. Fontaine, 5/20/93, 61 pp.

CBTS: This volume of data has been assigned MRID No. 428088-01. CBTS has the following comments on Miles's response:

(1) The material safety data sheets and the names and addresses of the suppliers of the raw materials used in the manufacture of MAT 7484 technical are adequate; these aspects of the deficiency are resolved.

(2) We accept as adequate for this petition the raw material specifications, quality assurance, and description of equipment provided in MRID 420054-01 and -02. Miles has been made aware (telecon, M. Mautz, 1/93) that, in future, a listing of all equipment (with descriptions) must be included in its format of a GRN 61-2 study.

(3) Miles has not yet responded to our request to explain certain aspects of the manufacturing process. What we wish clarified is detailed in the Confidential Appendix, which see. This portion of the deficiency is NOT yet resolved.

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.

(Note: If TGAI was not used, this study must be redone; see the Product Chemistry Guidelines, GRN 63-6.) This deficiency is not yet resolved.

2. The information provided in MRID 420088-02 (Miles Brochure No. 1828) for GRN 63-7 (density) is acceptable. This deficiency is resolved.
3. 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.

(Note: If acceptable information can not be provided, this study must be redone. The Product Chemistry Guidelines (GRN 63-12) specifically state: "Each substance for which a pH determination is required shall be diluted or dispersed with distilled water. The determination shall be made at 20°C or 25°C...." This deficiency is not resolved.

4. 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, which see. This deficiency is not yet resolved.
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 conducted in conjunction with the temporary tolerance petition (review of 5/18/93, M. Nelson, PP#2G4048). At such time as all deficiencies are resolved for PP#1F4025, a determination will be made as to whether an additional DRES run is appropriate.

RECOMMENDATIONS

For the reasons cited in Conclusions 1, 3, and 4 above, CBTS again recommends against the establishment of the **permanent** tolerances being proposed by the petitioner for residues of 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)".

ATTACHMENT: Confidential Appendix - 1 page.

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

H7509C:CBTS:MJN:mjn:CM#2:804:305-7324:4025MAT.PC2:7/29/93.
RDI:SecHd:RSquick:7/29/93:BrSrScientist:RALoranger(byDE):7/29/93.

DP#1F4025

Page 6 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.
-

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.
