PRODUCT INGREDIENT SOURCE INFORMATION IS NOT INCLUDED

DATE OUT: 12JUN/2001

SUBJECT: Product Chemistry Review Of: Manufacturing-Use Product [ ] End-Use Product [X]
DP BARCODE No.: 272011 EPA RECEIVED DATE: 04/FEB/2001 REG./File Symbol No.: 264-ATE
PRODUCT NAME: Charter Brand PB Fungicide MRIDs.:450428-01
COMPANY NAME: Aventis Crop Science USA LP Action Code: 100

FROM: Sami Malak, Chemist
Technical Review Branch/RD (7505C)

TO: 21 Mary Waller/Summer Gardner-Jenkins
Fungicide Branch/RD (7505C)

INTRODUCTION:

In a letter dated 31/JAN/2001, the applicant requested a FIFRA Section 3(c)(5) registration of subject product. Included with this action are: product chemistry data, product's label EPA received 04/FEB/2001, and a basic formulation, CSF dated 11/OCT/1999.

FINDINGS:

1a. The subject product is produced by an integrated production system, meaning that one of two technical sources in the product, triticonazole, is not registered. The product contains 12.5% thiram, Reg. No. [redacted] plus 1.25% triticonazole, Reg. No. 264-xxx.

1b. Charter Brand PB Fungicide is a liquid seed treatment that can be used for control of seed/seedlings diseases.

2. The submitted product chemistry data is adequate and support FIFRA Section 3(c)(5) registration of subject product.

3. Adequate analytical method is available for enforcement. The method, included with this submission in MRID #450428-01, also reviewed in this memorandum, is entitled "Determination of Triticonazole and Thiram by High Performance Liquid chromatography (HPLC) in Technical and Formulated Products."

4. The label claim nominal concentration of 12.5% thiram plus 1.25% triticonazole is consistent with that on the CSF, both are in compliance with the regulations of PR Notice 91-2. Further, the storage and disposal statement is in compliance with the regulations of 40CFR§156.10.

5. The submitted product's CSF a basic formulation dated 11/OCT/1999 was filled out correctly and completely and agree with the label claim nominal concentration as per the regulations of PR Notice 91-2. Further, the upper and lower certified limits are within the standard limits of 40CFR§158.175(b)(2). All ingredients claimed on the CSF are cleared for use in pesticide formulations.

CONCLUSIONS:

Pending registration of one of the two active ingredients in the product, triticonazole, we will have no objections for a FIFRA Section 3(c)(5) registration of subject product. Product's label and CSF are acceptable as per Findings 4 & 5 above.

REVIEW OF PRODUCT CHEMISTRY DATA:

1. A statement of data confidentiality dated 11/OCT/1999 was included with this submission claiming confidentiality of some of the data requirements on the basis of its falling within the scope of FIFRA§10(d)(1)(A), (B), or (C). Review of CBI information is to be found in Confidential Appendix A.

2. A GLP statement dated 11/OCT/1999 was included with this submission to the effect that some of the submitted studies were conducted in full compliance with GLP requirements of 40CFR§160.

DATA SUBMITTED

MRID #450428-01 The submitted study entitled: "EXP 81096A Product Chemistry, Data Requirement of OPPTS Series 830 Product Properties Test Guidelines, Group A & B", was authored by John Cookinham; Performed by Midwest Research Institute of Kansas City, Missouri; Completed on 08/JUL/1999 (52 pages).

Group A, Series 830-Product Identity, Composition, and Analysis (40 CFR 155, 160, 162, 167, 175 & 180)

830-1550 Product Identity and Composition

This product contains two technical grade of active ingredients, one of which is not registered, plus cleared inert ingredients (refer to product's CSF, dated 11/OCT/1999).

830-1600 Description of Materials Used to Produce the Product:
Refer to Confidential appendix A.

830-1650 Description of Formulation Process:
Refer to Confidential appendix A.

830-1670 Discussion of Formation of Impurities:
Refer to Confidential appendix A.

830-1700 Preliminary Analysis:
Refer to Confidential appendix A.

830-1750 Certified Limits:
Refer to Confidential appendix A.

830-1800 Enforcement Analytical Method:

Adequate analytical method is available for enforcement. The method, included with this submission MRID #450428-01, is entitled "Determination of Triticonazole and Thiram by High Performance Liquid chromatography (HPLC) in Technical and Formulated Products."
In this method the active ingredients are extracted and solvated in a mixture of dimethylformamide (DMF) and acetonitrile and reference standards are added. HPLC separation is followed by ultraviolet detection with calibration by internal standardization.

Method validation was performed by evaluation of standard curve data. Linearity was determined by preparing solutions of various concentrations for both analytical standards and evaluating the

resulting linear regression equations. Accuracy was determined from the recovery of the standard solutions. Precision was evaluated by preparing appropriate concentrations of the analytical standards, and sample stability was evaluated by analysis of one of the batches of the formulation at the end of the experimental period.

Data submitted on method validation as to accuracy, precision, linearity, and recovery are adequate. Sample calculations and chromtograms are included with this submission.

Group B, Series 830-Physical and Chemical Properties (40 CFR 158.190):

GUIDELINE REFERENCE NO.(GRN 830.)/TITLE	VALUE OR QUALITATIVE DESCRIPTION
6302 Color	Pink.
6303 Physical State	Liquid.
6304 Odor	No odor.
6314 Oxidation/Reduction: Incompatibility	No noticeable change in temperature or evolution of gas was observed for any of several oxidizing/reducing mixtures, except for a change in color and appearance with potassium permanganate indicating mild reactivity.
6315 Flammability/Flame Extension	202°F
6316 Explodability	NA
6317 Storage Stability	NA as per PR Notice 92-5.
6319 Miscibility	NA
6320 Corrosion Characteristics	Non corrosive.
6321 Dielectric Breakdown Voltage	Not recommended for use around electrical equipment.
7000 pH	4.5
7100 Viscosity	279 cP
7300 Density/Relative Density Bulk Density	9.3 lb/gal.

Confidential Appendix A

830-1600 Description of Materials Used to Produce the Product:

This product contains two technical grade of active ingredients, one of which is not registered, plus cleared inert ingredients (refer to product's CSF, dated 11/OCT/1999).

830-1650 Description of Formulation Process:

This product was formulated using a mixture of one registered technical grade of active ingredients and a second non-registered active ingredient plus cleared inert ingredients (refer to product's CSF dated 11/OCT/1999). In the process the appropriate amounts of each ingredient is added and [redacted].

830-1670 Discussion of Formation of Impurities:

The applicant reported no impurities ≥0.1% by weight were known to be formed during formulation and storage of the product.

830-1700 Preliminary Analysis:

Three batch analysis were performed and the results indicated an average thiram of 12.83% and that of triticonazole at 1.29%.

830-1750 Certified Limits:

The applicant reported the same ingredients at percentages and low/upper limits as those reported on product's CSF.

cc: S. Malak and Central File (Reg. No. 264-ATE).
7505C:RD:TRB:CM-2:Rm.268:s.m.:12/JUN/2001:703-308-9365:<264-ATE>.