

US EPA ARCHIVE DOCUMENT

DATE OUT: 08/JUN/2004

FEE: PRODUCT CHEMISTRY REVIEW OF: Manufacturing-Use [] End-Use Product [X]
DP BARCODE #: D299539 EPA RECEIVED DATE: 11/SEP/2003 FILE SYMBOL/REG: 100-RROE
PRODUCT NAME: Tilt Bravo SE MRID: 460797-01 & -02
COMPANY: Syngenta Crop Protection, Inc. FOOD USES [X] ACTION CODE: R31
PPC NUMBER OF THE TGAI IN THE PRODUCT: 081901, 122101 CASE NO.: 334429

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

SMB e/9/04

TO: 22 Cynthia Giles-Parker/Rosemary Kearns
Fungicide Branch/RD (7505C)

INTRODUCTION:

In a letter dated 09/SEP/2003, the applicant requested registration of subject product. In support of this action, the applicant included product chemistry data, a proposed basic CSF dated 29/APR/2003, a proposed label EPA received 12/SEP/2003, Formulator's Exemption Statement, Certificate With Respect to Citation of Data, and Data Matrix.

FINDINGS:

1. The subject product was produced by a non-integrated formulation system, meaning that the two active ingredients in the product are registered. The product contains 2.95 Propiconazole, [REDACTED] plus 38.5% Chlorothalonil, [REDACTED]
2. The subject product, a fungicide, is intended for control of diseases in crops.
- 3a. The applicant should be advised to submit product chemistry data identified in this application as data gaps, which are: storage stability (GRN 830.6317) and corrosion characteristics (GRN 830.6320).
- 3b. Except for the data gaps in Finding 3(a) above, the submitted product chemistry data is adequate and support registration of subject product.
4. Adequate analytical methods are available for enforcement. The methods were previously submitted and reviewed in connection with registration of the technical sources:
[REDACTED]
An analytical method was included with this submission, MRID #460797-01, entitled "Identification of the active ingredients by gas chromatography (capillary)." The method AF-1513/1, reviewed in this memorandum, determines the two active ingredients in the product, propiconazole and chlorothalonil.
5. The label claim nominal concentrations of 2.9% Propiconazole plus 38.5% Chlorothalonil are consistent with that in the CSF, both are in compliance with the regulations of PR Notice 91-2. Further, the storage and disposal statement and the physical or chemical hazards statement are in compliance with the regulations of 40CFR§156.78.
6. The proposed basic CSF dated 29/APR/2003 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

PRODUCT INGREDIENT SOURCE INFORMATION IS NOT INCLUDED

40CFR§158.175(b)(2).

CONCLUSIONS:

After resolving Finding 3(a) above, the TRB will have no objections for registration of subject product. The proposed basic CSF dated 29/APR/2003 are acceptable as per Findings 5 & 6 above.

REVIEW OF PRODUCT CHEMISTRY DATA:

1. A statement of data confidentiality dated 29/APR/2003 was included with this submission claiming confidentiality of some of the submitted data on the basis of its falling within the scope of FIFRA§10(d)(1)(A), (B), or (C). Review of CBI data has been removed to Confidential Appendix A.
2. A GLP statement dated 29/APR/2003 was included with this submission to the effect that some of the submitted studies were conducted in compliance with the GLP requirements of 40CFR§160.

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 registered technical grade of an active ingredients, plus cleared inert ingredient intended for food uses (refer to product's basic CSF dated 29APR/2003).

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 methods are available for enforcement. The methods were previously submitted and reviewed in connection with registration of the technical sources: [REDACTED]

An analytical method was included with this submission, MRID #460797-01, entitled "Identification of the active ingredients by gas chromatography (capillary)." The method, AF-1513/1, determines the two active ingredients in the product, propiconazole and chlorothalonil. In this method, the identity is confirmed when on two consecutive determinations the retention

PRODUCT INGREDIENT SOURCE INFORMATION IS NOT INCLUDED

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times recorded for the peak of the reference substances on the reference chromatogram deviate by not more than 0.2 minutes from those recorded for the corresponding peak on the test chromatograms. The retention times for propiconazole and chlorothalonil were reported at 5.28 & 3.1 minutes, respectively.

The methods were validated and the submitted data regarding recovery, precision, accuracy, reproducibility, and linearity are adequate. Sample calculations and chromatograms are included with this submission.

Identity, Composition, Formulation, and Analysis, Subgroup A, Series 830.1550 to 830.1800 (40 CFR 158.155 to 158.180)

Guideline Reference NO.(GRN 830.)/Title	Data Fulfilled	MRID No.
.1550 Product identity and composition	Y	460797-01
.1600 Description of materials used to produce the product	Y	460797-01
.1620 Description of production process	NA	
.1650 Description of formulation process	Y	460797-01
.1670 Discussion of formation of impurities	Y	460797-01
.1700 Preliminary analysis	NA	
.1750 Certified limits	Y	460797-01
.1800 Enforcement analytical method	Y	460797-01

Explanations: Y =The requirements were fulfilled; N = The requirements not fulfilled; N/A = Not applicable; G = Data gap; U = Requires upgrading; I = Incomplete or in progress; W = Waived.

Physical and Chemical Properties, Subgroup B, Series 830.6302 to -830.7300 (40 CFR 158.190)

The applicant complied with PR Notice 98-1 on self-certification of product chemistry data and submitted an abstract summary of product's physical/chemical properties in EPA Form 8570-36. A self certification statement, EPA Form 8570-37, dated 29APR/2003 was included with this submission. The data is summarized in the following table:

Guideline Reference NO.(GRN 830.)/Title	Data Fulfilled	Value or Qualitative Description	MRID No.
.6302 Color	Y	Light gray	460797-02
.6303 Physical state	Y	Liquid.	460797-02
.6304 Odor	Y	Paint	460797-02
.6314 Oxidation/reduction: Chemical incompatibility	Y	Not an oxidizing substance.	460797-02
.6315 Flammability/flame extension	Y	>212°F	460797-02
.6316 Explodability	Y	The product does not contain potentially explosive ingredients.	460797-02
.6317 Storage stability	I		
.6319 Miscibility	NA	Is not intended to be mixed with petroleum solvents.	
.6320 Corrosion characteristics	I		
.6321 Dielectric breakdown voltage	NA	Not recommended for use around electrical equipment.	
7000 pH	Y	5-7 (1% dispersion in water @ 25°C).	460797-02
.7100 Viscosity	Y	573 mPas @ 25°C	460797-02
7300 Density/relative density/bulk density	Y	10.5 lbs/gal @ 25°C	460797-02
Explanations: Y = The requirements were fulfilled; N = The requirements not fulfilled; N/A = Not applicable; G = Data gap; U = Requires upgrading; I = Incomplete or in progress; W = Waived.			

Page 5 is not included in this copy.

Pages ___ through ___ are not included in this copy.

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.
