

DATE OUT: 30/ SEPT / 2003

SUBJECT: PRODUCT CHEMISTRY REVIEW OF MP [] EP [X]
DP BARCODE No.: D290241 File Symbol No.: 100-RRTI
PRODUCT NAME: Quilt
COMPANY: Syngenta Crop Protection, Inc.
FOOD USE [X] INTEGRATED FORMULATION []
PCC: 122101, 128810; Decision No. 212036

FROM: Shyam Mathur, Team Leader
Product Chemistry Team
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SB Mathur
9-30-03
pm wall

INTRODUCTION:

The registrant has submitted product chemistry data in support of the registration application for the proposed fungicide Quilt. It is a broad spectrum, preventive fungicide with systemic and curative properties recommended for the control of many important plant diseases. The product chemistry data have been submitted under MRID Nos. 459164-01 and 459164-02. The registrant has submitted a CSF for basic formulation (dated 04/01/03, No. 262/1). The TRB has been asked to evaluate product chemistry data submitted and determine whether the product chemistry data submitted satisfy the data requirements for Sec 3 registration of the proposed product.

SUMMARY OF FINDINGS

1. The proposed product contains Propiconazole technical (Reg. No. 100-618, 95.0%) and Azoxystrobin technical (Reg. No. 100-1129, 96.0%) as the active ingredients with product label claims of 11.7% and 7.0% respectively.
2. The CSF for the basic formulation (No. 262/1, dated 4-01-03) is filled out correctly and completely. The nominal concentrations of the active ingredients concur with the product label claim nominal concentrations. The CSF is in compliance with PR Notice 91-2. All the inert ingredients used in the formulation are cleared by the Agency and are exempted from tolerance requirement for food use. The data submitted corresponding to the guideline reference 830.1550 (Product Identity & composition) and 830.1750 (Certified limits) satisfy the data requirements of 40CFR§158.155 and 158.175 respectively.
3. The data submitted corresponding to the guideline reference 830.1600 (description of materials used to produce the product) and 830.1650 (Description of formulation process) satisfy the data requirement 40CFR§158.160 and 158.165 respectively. [MRID No. 459164-01]
4. The data submitted corresponding to guideline reference 830.1670 (Discussion on the formation of impurities) satisfy the data requirements of and 40CFR§158.167. [MRID No. 459164-01]
5. The data submitted corresponding to the guideline reference 830.1800 (Enforcement analytical method) satisfy the data requirements of 40CFR§158.180. The capillary GC/FID with internal standard method was used to determine the active ingredients Propiconazole and Azoxystrobin in the end use product Quilt. [MRID No. 459164-01]

DP BARCODE No.: D290241 File Symbol No.: 100-RRT PRODUCT NAME: Quilt

6. The data submitted corresponding to 830 Series Subgroup B (Physical-Chemical properties) satisfy the data requirements of 40CFR§158.190. [MRID No. 459164-02]
7. The registrant has submitted the results of 14 days 54°C for 830.6317 (Storage stability) study and stated that long term study is in progress. [MRID No. 459164-02]
8. In regard to corrosion characteristics (830.6320) study, the registrant has informed that one year study is in progress and the short term (one month) physical evaluation did not indicate any signs of corrosion to the packaging material. [MRID no. 459164-02]

CONCLUSIONS:

The TRB has reviewed the product chemistry data submitted for the proposed end use product and has concluded that:

1. The product chemistry data submitted corresponding to 830 Series Subgroup A are acceptable.
2. The product chemistry data submitted corresponding 830 Series Subgroup B (Physical/Chemical properties) are acceptable except for 830.6317 (One year storage stability) and corrosion characteristics (830.6320).
3. The registrant is required to generate one year storage stability (830.6317) study for the proposed product under warehouse conditions. It is recommended that observations be made at 0, 3, 6, 9, and 12 months intervals. The corrosion characteristics (830.6320) study may be carried out concurrently. The registrant may request the PM for conditional registration while the study is in progress.
4. CSF for basic formulation (No. 262/1 dated 04-01-03) is acceptable.

2

DP BARCODE No.: D290241 File Symbol No.: 100-RRTI PRODUCT NAME: Quilt

PRODUCT CHEMISTRY DATA (SERIES 830 Subgroup A & Subgroup B)

Subgroup A	Data Required Fulfilled	MRID No.
830.1550. Chemical Identity (Basic CSF)	Y	04-01-03
830.1600. Beginning Materials	Y	459164-01
830.1650. Formulation Process	Y	" " "
830.1670. Discussion of Impurities	Y	" " "
830.1700. Preliminary Analysis	NA	
830.1750. Certified Limits (Basic CSF)	Y	04-01-03
830.1800. Enforcement Analytical Method	Y	459164-01

Subgroup B	Data Required Fulfilled	Value or Qualitat. Descrip.	MRID No.
830.6302. Color	Y	Light yellow	459164-02
830.6303. Physical State	Y	Liquid	" " "
830.6304. Odor	Y	Faint sweet odor	" " "
830.6314. Oxidation/Reduction Action	Y	None	" " "
830.6315. Flammability	Y	> 212°F	" " "
830.6316. Explodability	Y	Non-explosive	" " "
830.6317. Storage stability	I	1 yr in progress	" " "
830.6319. Miscibility	NA		
830.6320. Corrosion Characteristics	I	1 yr in progress	459164-02
830.6321. Dielec. Bkd. Vltg.	NA		
830.7000. pH	Y	6-8	459164-02
830.7100. Viscosity	Y	1.048 mPa s 20°C	" " "
830.7000. Density/Bulk Density	Y	8.86 lbs/gal 20°C	" " "

Explanations: Y = The Requirements Were Fulfilled; N = The Requirements Were Not Fulfilled; NA = Not Applicable; G = Data Gap; U = Requires Upgrading; I = Incomplete or In Progress; W = Waived.

DP BARCODE No.:D290241 File Symbol No.: 100-RRTIPRODUCT NAME: Quilt

Enforcement analytical method: (MRID No. 459164-01)

The active ingredients Propiconazole and Azoxystrobin were determined simultaneously in the end use product Quilt using capillary GC/FID with an internal standard.

Equipment and Parameters

Equipment: HP 5890 or 6890 gas chromatograph equipped with FID.
Column: J & W DB-5, 15 m x 0.25 mm id; 0.25µm film thickness
Column temperature: 200°C (hold 3 min) to 280°C (@ 40°C / min, hold 5 min)
Injector temperature: 285°C
Detector temperature: 300°C
Carrier gas: He (35 cm/sec)
Make up gas: Nitrogen (30 ml/min)
Split ratio: 50:1
Split flow: 45 ml / min
Run time: 10 min
Injection volume: 1.0 µL
Internal standard: 2 mg / ml dibutyl phthalate in acetone
Retention time:

Propiconazole (CGA64250, mixture of distereomers) - 4.86 / 4.91 min
Azoxystrobin (ASF819) - 8.14 min