FEE

DATE OUT: 24/JUL/2006

SUBJECT: **PRODUCT CHEMISTRY REVIEW OF MP [ ] EP [X]**
DP BARCODE No.: 326029 **File Symbol No.:** 264-IAE
PRODUCT NAME: Prosaro 421 SC Fungicide
COMPANY: Bayer CropScience LP
FOOD USE [X] **INTEGRATED FORMULATION [ ]**
PCC: 128997, 113961 **Decision No.** 363636

FROM: Debra Rate
Product Chemistry Team
Technical Review Branch/RD (7505C) 7/24/06

TO: Mary Waller / Lana Coppolino RM 21
Fungicide Branch / RD (7505C)

INTRODUCTION:
The registrant has submitted for review a basic CSF (dated 18/JUL/2006) and an alternate formulation CSF (dated 19/JUL/2006) for the proposed end-use product, Prosaro 421 SC Fungicide. The subject product uses tebuconazole (19%) and prothioconazole (19%) as its active ingredients (AIs). The registrant has provided MRID No. 467277-01 in support registration of the proposed end-use product. The technical review branch (TRB) has been asked to review the submitted data for acceptability.

SUMMARY OF FINDINGS
1. The proposed end-use product, Prosaro 421 SC Fungicide, uses tebuconazole (EPA Reg. No. 264-748, 95.37%) and prothioconazole (registration pending) as its active ingredients (AIs) with product label claims of 19% and 19%, respectively.

2. The registrant has submitted a CSF for basic formulation (dated 18/JUL/2006) for the proposed end-use product, Prosaro 421 SC Fungicide. The basic CSF is filled out correctly and completely. The nominal concentrations of the AIs concur with the product label claims nominal concentrations. The CSF is in compliance with PR Notice 91-2. All of the inert ingredients have been cleared by the Agency for preharvest use in pesticide formulations. The data submitted corresponding to guideline 830.1550(product identity and composition) and guideline 830.1750 (certified limits) satisfy the requirements of 40§CFR158.155 and 158.175, respectively.

3. The registrant has submitted a CSF for alternate formulation (dated 19/JUL/2006) for the proposed end-use product, Prosaro 421 SC Fungicide. The basic CSF is filled out correctly and completely. The nominal concentrations of the AIs concur with the product label claims nominal concentrations. The CSF is in compliance with PR Notice 91-2. All of the inert ingredients have been cleared for preharvest use by the Agency. The data submitted corresponding to guideline 830.1550(product identity and composition) and guideline 830.1750 (certified limits) satisfy the requirements of 40§CFR158.155 and 158.175, respectively.

4. The submitted alternate formulation CSF is in compliance with 40§CFR152.43. The basic and alternate formulations differ from each other only in the use and amount of various inert ingredients. See Confidential Appendix for the breakdown of the formulations.

5. The data submitted corresponding to the guideline reference 830.1600 (description of materials used to produce the product) satisfies the data requirements of 40§CFR158.160. [MRID No. 467277-01]

6. The data submitted corresponding to the guideline reference 830.1600 (description of materials used to produce the product) satisfies the data requirements of 40§CFR158.160. [MRID No. 467277-01]

7. The data submitted corresponding to guideline references 830.1650 (description of formulation process) satisfies the data requirements of 40CFR§158.165. [MRID No. 467277-01]

8. The data submitted corresponding to guideline references 830.1670 (discussion on the formation of impurities) satisfies the data requirements of 40§CFR158.167. No impurities of toxic concern were reported by the registrant. The registrant has stated that no reactions are expected between the AI, the impurities, the formulation ingredients or product packaging to form new impurities greater than 0.1%. [MRID No. 467277-01]

9. The data submitted corresponding to the guideline reference 830.1800 (enforcement analytical method) satisfies the data requirements of 40CFR§158.180. The active ingredients, tebuconazole and prothioconazole, were determined by high performance liquid chromatography (HPLC) with UV detection (225 nm). [MRID No. 467277-01]

10. The data submitted corresponding to 830 Series Subgroup B (physical-chemical properties) satisfy the data requirements of 40CFR§158.190, except for storage stability (830.6317) and corrosion characteristics (830.6320). [MRID No. 467277-01]

11. The ingredient and storage / disposal statement on the proposed label meet label requirements from a product chemistry point of view. However, two typos must be corrected in the chemical name of tebuconazole. The typos are highlighted in bold type:

alpha-[2-(4-chlorophe**n**yl)ethyl]-alpha-(1,1-dimethyl)-1***H***-1,2,4-triazole-1-ethanol

CONCLUSIONS:
The TRB has reviewed the submitted basic formulation CSF (dated 18/JUL/2006), alternate formulation CSF (dated 19/JUL/2006) and product chemistry data for the proposed end-use product, Prosaro 421 SC Fungicide and has concluded that:

1. The product chemistry data submitted corresponding to 830 Series Subgroup A are acceptable.

2. The CSF for basic formulation (dated 18/JUL/2006) is acceptable, pending the registration of one of the technical sources.

3. The CSF for alternate formulation (dated 19/JUL/2006) is acceptable, pending the registration of one of the technical sources.

4. The product chemistry data submitted corresponding to 830 Series Subgroup B (physical/chemical properties) are acceptable, except for those pertaining to storage stability (830.6137) corrosion characteristics (830.6320).

5. The registrant must submit the results of the one year storage stability (830.6317) and the corrosion characteristics (830.6320) studies (time points of 0,3,6,9 and 12 months) to the Agency on completion. The Agency requests that the data for these studies be submitted both electronically and in paper form.

6. The ingredient statement on the label must be revised according to Finding #8.

BARCODE No.: 326029 **File Symbol No.:** 264-IAE **PRODUCT NAME:** Prosaro 421 SC Fungicide

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

Subgroup A	Data Required Fulfilled	MRID No.
830.1550. Chemical Identity (Basic CSF)	Y	CSF (dated 18/JUL/2006)
830.1600. Beginning Materials	Y	467277-01
830.1650. Formulation Process	Y	467277-01
830.1670. Discussion of Impurities	Y	467277-01
830.1700. Preliminary Analysis	NA	
830.1750. Certified Limits (Basic CSF)	Y	CSF (dated 18/JUL/2006)
830.1800. Enforcement Analytical Method	Y	467277-01

Subgroup B	Data Required Fulfilled	Value or Qualitat. Descrip.	MRID No.
830.6302. Color	Y	Off White	467277-01
830.6303. Physical State	Y	Liquid	467277-01
830.6304. Odor	Y	Latex paint-like odor.	467277-01
830.6314. Oxidation/Reduction Action	NA	Product does not contain any ingredient considered to be an oxidizing or reducing agent.	467277-01
830.6315. Flammability	NA	Product is not a combustible liquid or gas.	467277-01
830.6316. Explodability	NA	Not applicable. No impact explosive characteristics.	467277-01
830.6317. Storage stability	I	In progress.	467277-01
830.6319. Miscibility	NA	Product not intended for dilution with petroleum solvents.	467277-01
830.6320. Corrosion Characteristics	I	In progress.	467277-01
830.6321. Dielec. Bkd. Vltg.	NA	Product is not intended for use around electrical equipment.	467277-01
830.7000. pH	Y	pH = 7.8 (10% aqueous suspension) (expected range 7.5 to 7.9)	467277-01
830.7100. Viscosity	Y	413 cps	467277-01
830.7300. Density/Bulk Density	Y	1.112 g / cc @ 20°C	467277-01

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.

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830.1800 Enforcement Analytical Method: [MRID No. 467277-01]

The registrant has submitted an HPLC / UV (225nm) method for the determination of the AIs, tebuconazole and prothioconazole.

Reagents:
Acetonitrile
Acetonitrile: Water: Methanol (55:35:10)
Diethyl phthalate, 99%
Diethyl phthalate, 0.4% (v/v) in acetonitrile
Methanol, HPLC grade
Phosphoric acid
Prothioconazole, standard of known purity
Tebuconazole, standard of known purity
Water, deionized
Water, acidified, 0.1%

Equipment:

Filter:	0.45 µm Target PTFE or equivalent
HPLC Column:	Agilent 250 m X 4.6 mm i.d. Rx-C18
Laboratory Data System:	Agilent ChemStation or equivalent
HPLC	Agilent Model 1100 equipped with variable wavelength detector, autoinjector, or equivalent equipment.
Ultrasonic bath	

Conditions:

Detector range:	1.0 V
Flow Rate:	1.4 ml / min
Detector Response:	1 sec
Injection Volume:	5 µl
Stop Time:	9 minutes
Range:	2.0 AUFS
Wavelength:	225 nm

CONFIDENTIAL APPENIDX:

BARCODE No.: 326029 **File Symbol No.:** 264-IAE **PRODUCT NAME:** Prosaro 421 SC Fungicide

The following table shows the breakdown of changes between the basic formulation CSF (dated 18/JUL/2006) and the alternate formulation CSF (dated 19/JUL/2006):

Ingredient	Purpose in formulation	Basic CSF (dated 18/JUL/2006)	Alternate CSF (dated 19/JUL/2006)
[redacted]			
Total:		**59.82%**	**59.82%**

Inert ingredient information may be entitled to confidential treatment

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Page _____ is not included in this copy.

Pages 6 through 11 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.

__X__ 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.

_____ Internal deliberative information.

_____ Attorney-Client work product.

_____ Claimed Confidential by submitter upon submission to the Agency.

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.
