DATE OUT: 19/JUN/2000

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: Manufacturing-Use Product [ ] End-Use Product [X]
BARCODE No.:263584 **EPA RECEIVED DATE:**21/JAN/2000 **REG./File Symbol No.:** 100-OAA
PRODUCT NAME: Stratego, 11.4% each of Trifloxystrobin & Propiconazole **Action Code:**170 **COMPANY NAME:** Novartis Crop Protection, Inc. **MRID:** 450254-01 to -02

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

TO: 22 Cynthia Giles-Parker/Janet Whitehurst
Fungicide Branch/RD (7505C)

INTRODUCTION:

In a letter dated 24/JAN/2000, the applicant requests FIFRA Section 3(c)(5) registration of subject product. Included with this action are: product chemistry data, Certification With Respect to Citation of Data, Data Matrix, product's label EPA received 28/JAN/2000, and CSF a basic formulation dated 22/OCT/1999

FINDINGS:

1. This product is produced by a non-integrated formulation system, meaning that the two active ingredients in the product are registered. The subject product, referred to as CGA-64250/CGA-279202 250 EC, contains 11.43% Propiconazole Technical, Reg. No. 100-618 plus 11.4% Trifloxystrobin Technical, Reg. No. 100-918.

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

3. A capillary gas chromatography analytical method, AF-1383/1, is recommended for enforcement. The method entitled "Identification of the Active Ingredients, CGA-64250/CGA279202 in Formulation (A-9525E), by Capillary Gas Chromatography", is authored by Drs. D. R. Stubbs & N. Johnson dated 21/APR/1999. The method is described in detail in this memorandum, also included in MRID #450254-01, along with validation data, sample chromtaograms and sample calculation.

4. The label ingredient statement and the storage and disposal statement satisfy the requirements of 40CFR§156.10. Further, the nominal concentrations of the active ingredient on product's label is consistent with that on the CSF in compliance with the regulations of PR Notice 91-2. No physical or chemical hazards are anticipated from the use of this product (solid formulation).

5. The submitted product's CSF, a basic formulation dated 22/OCT/1999, was filled out correctly and completely and the nominal concentration of the active ingredient is in agreement 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 intended for food uses.

CONCLUSIONS:

The applicant has satisfied product chemistry data requirements for a FIFRA Section 3(c)(5) registration of subject product. Product's label and CSF are acceptable as per Findings 4 & 5 above.

DETAILED CONSIDERATIONS

REVIEW OF PRODUCT CHEMISTRY DATA:

1. A statement of data confidentiality dated 22/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 22/OCT/1999 was included with this submission to the effect that descriptive studies do not fall under the compliance of GLP requirements of 40CFR§160.

DATA SUBMITTED

MRID #450254-01 The submitted study entitled "CGA-64250/CGA-279202 250 EC (A9525E), Product Chemistry Group A Data Requirements", was authored by Anthony Hipps, performed by Novartis Crop Protection, Inc. of Greensboro, NC; Completed on 19/OCT/1999 (38 pages).

MRID #450254-02 The submitted study entitled "CGA-64250/CGA-279202 250 EC (A9525E), Product Chemistry Group B Data Requirements", was authored by Anthony Hipps, performed by Novartis Crop Protection, Inc. of Greensboro, NC; Completed on 22/OCT/1999 (6 pages).

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

830-1550 Product Identity and Composition

The subject product, referred to as CGA-64250/CGA-279202 250 EC, contains

11.43% Propiconazole Technical, Reg. No. 100-618 plus 11.4% Trifloxystrobin Technical, Reg. No. 100-918.

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: MRID #447233-01.

A capillary gas chromatography (CGC) analytical method, AF-1383/1, is recommended for enforcement. The method entitled "Identification of the Active Ingredients, CGA-64250/CGA279202 in Formulation (A-9525E), by Capillary Gas Chromatography", is authored by Drs. D. R. Stubbs & N. Johnson dated 21/APR/1999. The method is described in detail in this memorandum, also included in MRID #450254-01, along with validation data, sample chromtaograms and sample calculation.

The CGC parameters are as follows:

Chromatograph: Hewlett Packard HP 6890 A

Detector: FID, output voltage = 1V

Integrator: X-Chrom Ver 2.1 lb (by Lab Systems), AT = 32

Column: Fused silica, 15 m length, 0.25 mm i.d.
stationary phase: DB-5
film thickness: 0.25 µm
available form: J & W Scientific, Part No. 122-5012

Column temperature: Hold 1.2 minutes isothermal at 170°C,°C, then heat with 2.5°C/minute to 200°C, then with 17°C/minute to 260°C, hold 3 minutes isothermal at 260°C.

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Detector temperature: 280°C

Injector temperature: 200°C

Carrier gas: helium, linear velocity ~50 cm/second at 260°C

Split flow: -80 ml/minute

Split ratio: 50:1

Make-up gas: nitrohgen, total flow rate 30 ml/minute (carrier + make-up)

Sensitivity: range 1

Size of Sample: 10 µl of reference/test solution.

Flow Rate: 1 µl/minute

Duration of Chromatography: Approximately 23 minutes

The method was validated and method recovery was reported at more than 97 to 103%. Method accuracy and precision were adequate. Further specificity was determined by demonstrating the absence of any interference.

Sample chromtograms and calculations are included with this submission.

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

The applicant complied with PR Notice 98-1 and submitted the needed information on EPA Form 8570-36. A signed and dated (26/OCT/1999) self-certification statement, EPA Form 8570-37, was also included. Summary of the physical/chemical properties on EPA Form 8570-36 is adequate and is appended to this memorandum (one page).

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Page _____ is not included in this copy.

Pages 5 through 6 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.

_____ 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.