

US EPA ARCHIVE DOCUMENT

DATE OUT: May 1, 2003

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: Manufacturing Use Product [ ],  
End Use Product [ X ]

BARCODE No.: D289698 EPA RECEIVED DATE: 04/23/03

EPA Reg. No.: 100-987 PRODUCT NAME: Brodifacoum Technical

MRIDs: 458594-01, plus letter with attachments

COMPANY NAME: Syngenta Crop Protection, Inc.

Action Code: 674

FROM: Bentley C. Gregg, Ph.D., Product Chemist  
Product Chemistry Team  
PRB/SRRD (7508C)

*Bentley C. Gregg*  
*May 1, 2003*

TO: Venus Eagle-Kunst, CRM  
Product Reregistration Branch  
Special Review and Reregistration Division (7508C)

#### INTRODUCTION:

The registrant, Syngenta Crop Protection, Inc., submitted a letter with explanatory materials, including a revised Confidential Statement of Formula (CSF; dated 11 April 2003), pages from a previously submitted MRID (129706), and a revised draft label (pin-punched received date 4/23/03), in support of a request for FIFRA Section 4 reregistration of their end use product, **Brodifacoum Technical**, EPA Reg. No. 100-987.

A Reregistration Eligibility Decision (RED), Case # 2755, was issued in August 1998 for the Technical Grade Active Ingredient (TGAI), Brodifacoum, which has the chemical name: 3-(3-(4'-Bromo-(1,1'-biphenyl)-4-yl)-1,2,3,4-tetrahydro-1-naphthalenyl)-4-hydroxycoumarin. The RED indicated that the generic data concerning the physical/chemical properties of the active ingredient, brodifacoum, were acceptable, but that additional data were required for the specific products, including a revised CSF, a revised product label, and additional data regarding the product chemistry (such as production methods, analytical procedures, and physical and chemical properties data). The registrant has submitted various information since the RED was issued, and the Agency has evaluated and accepted these data in Product Chemistry reviews by Paul Horng, dated 6/MAR/02 and 14/JAN/2003. Based on the information presented in these Product Chemistry reviews, it was concluded that the registrant still had a requirement to submit acceptable data for Guideline 830-1600, Description of Materials Used to Produce the Product, as well as an acceptable CSF and a revised label with a corrected percent nominal concentration. These materials were reviewed in a Product Chemistry review by Bentley C. Gregg (dated March 27, 2003), and various deficiencies were identified in the information on the production process, formation of impurities, CSF, and label.

#### FINDINGS:

1. Except for providing the information concerning the Description of Materials Used to Produce the Product, an acceptable CSF, a revised label, and certain other newly

identified data gaps, this Product Chemistry review concludes that the physical and chemical property data previously submitted are adequate, and support the reregistration requirements for the end use product, Brodifacoum Technical (EPA Reg. No. 100-987).

2. The registrant submitted a photocopy of four pages (pp. 4-7) from a previously submitted MRID (Accession No. 129706), pages which were illegible in the blow-back from the microfiche copy available from Information Services. These pages clearly show the initial eight (8) stages of the production process, thus, providing the required information concerning Guideline 830-1620, Discussion of Production Process. These pages also include information on the relative toxicity of the two isomeric forms of brodifacoum, addressing another issue in this reviewer's March 27, 2003 Product Chemistry review regarding Good Management Practices in the production processing, under the section on Preliminary Analysis. The information in the pages provided now satisfies the issues raised in Finding 2 of the March 27, 2003 Product Chemistry review.

The registrant also indicated in the letter dated April 21, 2003, that a new production process is under development, and that new product chemistry volumes will be submitted "in late summer of this year (but, no later than 12/31/03)." Hence, this review only references the submitted pages, and does not present the flow diagram for the existing multi-stage production in a Confidential Appendix; however, when the new submission is received from the registrant, the new, streamlined process will be reviewed in detail.

3. The registrant has also submitted a revised CSF (Basic formulation, dated 11 April 2003). This CSF corrects various issues identified in the Product Chemistry review dated March 27, 2003, including problems regarding the Upper Certified Limit for the active ingredient, listed as [REDACTED] and the Lower Certified Limit for the combined Process Related Impurities, listed as [REDACTED] these Certified Limits are now listed as [REDACTED] respectively. (These are the only apparent changes in the CSF dated 11 April 2003, compared with the previously reviewed CSF dated 11 Feb. 2003). The March 27, 2003 Product Chemistry review discussed the regulations listed at 40 CFR 158.175 (b)(2) for certified limits, but acknowledged that technical formulations differ from end-use formulations in the inherent situation that each batch run represents a unique synthesis. These issues were also orally discussed between the registrant and this reviewer in a telephone call, initiated by the registrant on April 10, 2003. Moreover, in their letter dated April 21, 2003, the registrant has submitted an attachment, "Explanation of the Limits for Impurities." Based on the technical points raised, this review now concurs that the registrant has presented sufficient justification for the various Certified Limits reported for the impurities and unreacted starting materials. Thus, the revised CSF (dated 11 April 2003) is now deemed to be acceptable.
4. The registrant has submitted a revised label (pin-punched received date April 23, 2003), on which the nominal concentrations of the active ingredient (Brodifacoum Technical) and the Inert Ingredients are now 95% and 5%, respectively. This submission corrects the deficiency identified in Finding 5 of the March 23, 2003 Product Chemistry review.

Manufacturing process information not included.

5. The previous Product Chemistry reviews (Paul Horng, dated 14/JAN/2003, and Bentley C. Gregg, dated March 27, 2003) requested certain changes in Storage and Disposal statement on the draft label (i.e., delete the sentence "Do not reuse empty container", and place the entire Storage and Disposal statement in a box). These deficiencies have now been addressed. In addition, the label indicates the packaging for the Technical product may be in either a metal container and plastic bag (as indicated in the Storage and Disposal Statement), thus clarifying an question raised in the March 27, 2003 Product Chemistry review.

### CONCLUSIONS:

With this submission, the registrant has now satisfied the product chemistry requirements for reregistration of the end use product, **Brodifacoum Technical**, Reg. No. 100-987.

Reviewer and Central File (Reg. No. 100-987).

7508C:SRRD:PRB:CM-2: B.C.G.: 05/01/03:703-308-8178:<100-987>