

DATE OUT: 16/OCT/2003

SUBJECT: PRODUCT CHEMISTRY REVIEW OF Technical Product [x], End-Use Product []
Data Package No. :294165 ; EPA RECEIVED DATE: 03/OCT/03 ; EPA REG./File Symbol No.: 100-987;
PRODUCT NAME: Brodifacoum Technical ; COMPANY NAME: Syngenta Crop Protection, Inc.; MRID #:
418922-01, -02, 460135-01 and 460581-01 ; Action Code: 675

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INTRODUCTION:

The registrant, Syngenta Crop Protection, Inc., responded to our previous memorandum (Paul Horng; D287736; 14/JAN/03) by submitting additional product chemistry data in MRID # 460135-01 and 460581-01, to fulfill the product chemistry data requirements for reregistration of the Brodifacoum Technical, EPA Reg. No. 100-987.

FINDINGS:

1. The submitted data in MRID # 460135-01 and 460581-01 satisfy the data requirements for the Guideline 61-2a (830-1600, Description of Materials Used to Produce the Product), 61-2b (830-1620, Description of Production Process), 61-3 (Discussion of Formation of Impurities), 62-1 (830-1700, Preliminary Analysis), 62-2 (830-1750, Certified Limits), and 62-3 (830-1800, Enforcement Analytical Method).

The revised concentrations of the active ingredient (Brodifacoum Cis form and Brodifacoum Trans form) from the preliminary analysis using five batches of TGA1 34, 36, 48, 49, and 50 were 97.9, 96.2, 99.4, 98.4, and 98.4%, respectively, with a mean concentration of 98.06%.

2. The revised CSF, a basic formulation dated 18/OCT/2003, has been filled out completely and accurately. The nominal concentration of the active ingredient in the CSF agrees with the data from the preliminary analysis. The CSF is acceptable.

3. A minor revision is required in the draft label. (1) The nominal concentration of Brodifacoum must be changed from 90.0 to 98.0%. (2) The concentration of Inert Ingredient must be changed from 10.0 to 2.0%. (3) The Storage and Disposal Statement must be placed in a box of solid line to increase its prominence.

CONCLUSION:

The registrant has satisfied all product chemistry data requirements for reregistration of this product. The Agency will have no objection to the reregistration of the Brodifacoum Technical, EPA Reg. No. 100-987.

Group A. Product Identity, Composition, Manufacturing, Certified Limits, and Analytical Method.

Guidelines and description	MRID #	Has the data requirement been fulfilled
830-1550 <u>Product Identity and Composition</u>	129706	Yes
830-1600 <u>Description of Materials Used to Produce the Product.</u>	460135-01	Yes
830-1620 <u>Description of Production Process.</u>	460581-01 129706	Yes
830-1670 <u>Discussion of Formation of Impurities</u>	460581-01 129706	Yes
830-1700 <u>Preliminary Analysis.</u>	460581-01	N/A
830-1750 <u>Certified Limits.</u>	460581-01	Yes
830-1800 <u>Enforcement Analytical Method:</u>	460581-01 129706	Yes

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

GUIDELINE REFERENCE NO.(GRN)/TITLE 830-	VALUE OR QUALITATIVE DESCRIPTION/ METHODS USED WHERE APPLICABLE AND REFERENCES	MRID #	Has the Data Requirement Been Fulfilled
-6302 Color.	Cream color.	418922-01	Yes
-6303 Physical State.	Fine powdery solid.	418922-01	Yes
-6304 Odor.	Waived. The registrant requested waiver for the data requirement because the TGAI is categorized as Class I in Inhalation Toxicity.	Waived	
-6313 Stability to Normal & Elevated Temperature, and to Metals & Metal Ions.	The concentration of TGAI was found to be at 95.5% and 95.0% after storage at 54°C and -20°C for 14 days. Brodifacoum TGAI (0.1g) was exposed to control, aluminum, iron granules, aluminum acetate, and iron acetate at 20C/50% RH and 38C for 7 and 14 days. No loss in concentration of the active ingredient was observed after the above exposure conditions.	418922-01	Yes
-7000 pH	3-5 (1% in aqueous solution at 20°C).	418922-01	Yes
-7050 UV/Vis Light Absorption	Absorption Maximum at 205 nm in methanol solution.	418922-01	Yes
-7200 Melting Point	201-205°C.	418922-01	Yes
-7300 Density.	1.42 g/mL at 25°C.	418922-01	Yes
-7370 Dissociation Constant in Water.	N/A, the water solubility of this TGAI is too low. In addition, the TGAI is neither an acid nor a base. It is not dissociated in water.	N/A	N/A
-7550/7560/7570 n-Octanol/Water Partition Coefficient	log Kow= 8.48	481922-02	Yes
-7840/7860 Solubility	The solubilities to organic solvents, such as hexane, toluene, dichloromethane, acetone, ethyl acetate, ethyl acetate, acetonitrile, and methanol in the order are 0.088, 7.2, 50, 23, 12,3.2, and 2.7 (g/L), respectively. The water solubility is 3.8×10^{-3} mg/L (pH 5.2); 240×10^{-3} mg/L (pH 7.4); 10000×10^{-3} mg/L (pH 9.3).	481922-01 481922-02	Yes
-7950 Vapor Pressure	10^{-9} kPa at 20°C.	481922-02	Yes

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Pages 4 through 6 are not included in this copy.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

 X Identity of product impurities.

 X 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.
