US EPA ARCHIVE DOCUMENT

1-14-2003

DATE OUT: 14/JAN/2003

SUBJECT: **PRODUCT CHEMISTRY REVIEW OF Technical Product [x], End-Use Product []**
BARCODE No. :D287736; D281104 ; **CASE No.**: 025669 ;**EPA RECEIVED DATE**: 16/DEC/01 ; **EPA REG./File Symbol No.**: 100-987; **PRODUCT NAME**: Brodifacoum Technical ; **COMPANY NAME**: Syngenta Crop Protection, Inc.,; **MRID #**: 129706, 418922-01,-02; 458321-01 ; **Action Code**: 675

FROM: Paul Horng, Ph. D., Environmental Scientist Paul Horng
Product Chemistry Team
Product Reregistration Branch (7508C)
Special Review and Reregistration Division
Office of Pesticide Programs
USEPA

TO: Venus Eagle-Kunst, CRM
Product Reregistration Branch (7508C)
Special Review and Reregistration Division
Office of Pesticide Programs
USEPA

INTRODUCTION:

The registrant, Syngenta Crop Protection, Inc., responded to our previous memorandum (Paul Horng; D281104; 6/MAR/02) by submitting additional product chemistry data in MRID # 458321-01, to fulfill the data requirements for reregistration of the Brodifacoum Technical, EPA Reg. No. 100-987.

FINDINGS:

1(a). The submitted data in MRID # 458321-01 satisfy the data requirements for the Guidelines 63-2 (830-6302, Color), 63-3 (830-6303, Physical State), 63-4 (830-6304, Odor), 63-7 (830-7300, Density), 63-12 (830-7000, pH), 63-13 (830-6313, Stability to Normal and Elevated temperature, to Metals and Metal Ions). The data requirements for the Guidelines 63-14 (830-6314, Oxidation/Reduction Action), 63-15 (830-6315, Flammability), 63-16 (830-6316, Expodability), 63-18 (830-7100, Viscosity), 63-19 (830-6319, Miscibility), 63-21 (830-6321, Dielectric Breakdown Voltage) are not applicable to this product and are waived.

1(b). No data have been submitted for the Guideline 61-2a (830-1600, Description of Materials Used to Produce the Product). The data requirement remains outstanding.

2. The submitted CSF, a basic formulation dated 21/DEC/01, is not acceptable. The preliminary analysis data indicated the nominal concentration of the active ingredient (combination of cis-brodifacoum and trans-brodifacoum) in the technical is about 95.0% (actually, it was 94.9%. For easy calculation, it can be run up to 95.0%). Thus, the CSF must be revised in the same way as describes below: (1) The amount, percent by weight, upper limit, and lower limit of the active ingredient, brodifacoum, in the columns # 13a, # 13b, # 14a, and # 14b of the first row of the CSF must be changed to [redacted] 95.0, 97.85, and 92.15%, respectively. (2) The amount, percent by weight, upper limit, and lower limit of the processed related impurities in the columns # 13a, # 13b, # 14a, and # 14b of the second row of the CSF must be changed to [redacted] 5.0, 5.25, and 4.75%, respectively. (3) The registrant must list percent by weights and upper limits of the major impurities on the CSF and make them close to 5%.

3. A minor revision is required in the draft label. (1) The nominal concentration of brodifacoum must be changed from 90.0 to 95.0%. (2) The concentration of Inert Ingredient must be changed from 10.0 to 5.0%. (3) For consistency with other product, the subheading "Prohibition" and the sentence "Do not reuse empty container"

Manufacturing process information not included.

under this subheading should be deleted. (4) The Storage and Disposal Statement must be placed in a box of solid line to increase its prominence.

CONCLUSION:

Except for the data gap noted in Finding # 1(b), and some revisions are required for the CSF as noted in Finding # 2, the registrant has satisfied all product chemistry data requirements for reregistration of this product. Once the outstanding data have been submitted and satisfied; the revisions of the CSF have been made, the Agency will have no objection to the reregistration of the Brodifacoum Technical, EPA Reg. No. 100-987.

Group B: Series 830- Physical and Chemical Properties (40 CFR 158.190)
MRID # 449922-01.

GUIDELINE REFERENCE NO.(GRN)/TITLE 830-	VALUE OR QUALITATIVE DESCRIPTION/ METHODS USED WHERE APPLICABLE AND REFERENCES	Comments
-6302 Color.	Cream color.	A
-6303 Physical State.	Fine powdery solid.	A
-6304 Odor.	Not required as per PR Notice 92-5.	NR
-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.	A.
-7000 pH	3-5 (1% in aqueous solution at 20°C).	A
-7050 UV/Vis Light Absorption	Absorption Maximum at 205 nm in methanol solution.	A
-7200 Melting Point	201-205°C.	A
-7300 Density.	1. 42 g/mL at 25°C.	A
-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
-7550/7560/7570 n-Octanol/Water Partition Coefficient	log Kow= 8.48	A
-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).	A
-7950 Vapor Pressure	10^{-9} kPa at 20°C.	A
-6314 Oxidation/ Reduction Action	N/A, no evidence of oxidizing properties.	N/A
-6315 Flammability	N/A, the product contains no combustible liquid.	N/A
-6316 Explodability	N/A, no evidence of explodability.	N/A

-6317 Storage stability	The data can be substituted by the data in the Guideline 830-6313 Stability. Accelerated storage stability data are determined to be acceptable.	A
-7100 Viscosity	N/A, the product is not a liquid.	N/A
-6319 Miscibility	N/A, the product is not a liquid.	N/A
-6320 Corrosion Characteristics	The TGAI is stable in close contact with aluminum, iron filings, aluminum acetate, and ferric acetate at 20C and at 38C for 7 and 14 days.	A
-6321 Dielectric Breakdown Voltage	N/A, the product is not used around the electric equipment.	N/A

A: acceptable; N/A: not applicable; Gap: data gap; NR: not required.

D287736 ; D281104
BRODIFACOUM

Page _____ is not included in this copy.

Pages 5 through 7 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.

X Description of the product manufacturing process.

X 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.