DATE OUT: 6/MAR/2002

SUBJECT: PRODUCT CHEMISTRY REVIEW OF Technical Product [x], End-Use Product []
BARCODE No. : 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; **Action Code:** 674

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INTRODUCTION:

The registrant, Syngenta Crop Protection, Inc., cited the product chemistry data in MRID # 129706, 418922-01, and -02; the Confidential Statement of Formula (CSF), a basic formulation dated 21/DEC/01; and a draft label received by the Agency on 26/DEC/01; requesting for reregistration of the manufacturing-use product, Brodifacoum Technical, EPA Reg. No. 100-987.

FINDINGS:

1. A Reregistration Eligibility Decision (RED), Cases # 2100, 2205, 2755, 2760, 2765, and 2810, was issued August 3, 1998 for the Technical Grade Active Ingredients (TGAI) chlorophacinone, diphacinone, brodifacoum, bromadiolone, and bromethalin. The Agency has completed the Reregistration Eligibility Decision and determined that these chemicals, labeled and used as specified in this Reregistration Eligilibility Decision document, will not pose unreasonable risk or adverse effects to humans or the environment. Therefore, the Agency concludes that products containing brodifacoum, bromethalin, bromadicolone, chlorophacinone, and diphacinone and its sodium salts, are eligible for reregistration. The Agency has also determined that field-bait uses containing more than 0.005% chlorophacinone and diphacinone and its sodium salt are eligible for reregistration. The Agency has also determined that all used pival and its sodium salt are ineligible for reregistration and are to remain suspended. The generic data bases of product chemistry supporting the reregistration of brodifacoum, bromethalin, bromadicolone, chlorophacinone, and diphacinone have been determined to be substantially complete. No data gap was cited.

2(a). Except for the data gap noted in Finding # 2(b), the submitted data in MRID # 129706 satisfied the data requirement. for the Guidelines 61-1 (830-1550, Product Identity and Composition), 61-2b (830-1620, Description of Manufacturing Process), 61-3 (830-1670, Discussion of Formation of Impurities), 62-1 (830-1700, Preliminary Analysis), 62-3 (830-1800, Enforcement Analytical Method). The submitted data in MRID # 418922-01 satisfy the data requirements for the Guidelines 63-2 (830-6302, Color), 63-3 (830-6303, Physical State), 63-5 (830-7200, Melting Point), 63-7 (830-7300, Density), 63-8 (830-7840/7860, Solvent Solubility), 63-12 (830-7000, pH), and partial of 63-13 (830-6313, Stability to Elevated Temperature). The submitted data in MRID # 418922-02 satisfy the data requirements for the Guidelines 63-8 (830-7840, Water Solubility), 63-9 (830-7950, Vapor Pressure), and

63-11 (830-7550/7560/7570, n-Octanol/Water Partition Coefficient), and 830-7050, UV/Vis Absorption . The data requirement for the Guideline 63-10 (830-7370, Dissociation Constant in Water) is not applicable to this product and is waived. The data requirement for the Guideline 63-4 (830-6304, Odor) is waived because the toxicity of the TGAI may be harmful to human when inhales directly to the chemical. The data requirement for the Guideline 62-2 (830-1750, Certified Limits) depends upon the approval of the CSF.

2(b). No data have been submitted for the Guidelines 61-2a (830-1600, Description of Materials Use to Produce the Product), 63-13 (830-6313, Stability to Sunlight, Metals and Metal Ions). These data requirements remain outstanding.

3(a). The normal distribution of the preliminary analysis indicated that the nominal concentration of the active ingredient (combination of cis-brodifacoum and trans-brodifacoum) should be set at 95.0% (actually, it was 94.9%. For easy calculation, it can be run up to 95.0%). The concentrations of impurities should be set approximately at 5.0%.

3(b). As mentions in 3 (a), the submitted CSF, a basic formulation dated 21/DEC/01, should be revised in accordance with the following ways. (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 9500, 95.0, 98.8, and 91.2%, respectively. In this way a ± 4% of variation from the nominal concentration is allowed for this product. (2) The amount, percent by weight, upper limit, and lower limit of the related impurities in the columns # 13a, # 13b, # 14a, and # 14b of the second row of the CSF must be changed to 500, 5.0, 5.25, and 4.75%, respectively. (3) The registrant must list the percent by weights and upper limits of the major impurities as shown on the preliminary analysis on the CSF to make them a total 5%.

4(a). 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" 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.

4(b). Since the label requirements are still being developed, the Agency will request new labeling for these products when the Rodenticide Cluster RED document are amended. Label review related to product chemistry sections will be conducted until the Rodenticide Cluster RED has been amended.

CONCLUSION:

Except for some data gaps noted in Finding # 2(b), the registrant has satisfied all product chemistry data requirements for reregistration of this product. Once the outstanding data have been submitted and satisfied; the Rodenticide Cluster RED has been amended, and the product label related to the product chemistry sections satisfy the new label requirements, the Agency will have no objection to the reregistration of the Technical product, 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 Sunlight, 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. No data had been provided for the stability to sunlight, and stability to metals and metal ions.	Additional data are required.
-7000 pH	3.8 (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 x 10-3 mg/L (pH 5.2); 240 x 10-3 mg/L (pH 7.4); 10000 x 10-3 mg/L (pH 9.3).	A
-7950 Vapor Pressure	10^{-9} kPa at 20°C.	A

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

Page _____ is not included in this copy.

Pages __4__ through __6__ are not included in this copy.

The material not included contains the following type of information:

__X__ Identity of product inert ingredients.

__X__ 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.

__X__ 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.