

DATE OUT: 5/MAR/2002

SUBJECT: PRODUCT CHEMISTRY REVIEW OF Manufacturing Use Product [], End-Use Product [x]
BARCODE No. : D281281 ; CASE No.: 006559 ; EPA RECEIVED DATE: 08/JUN/00; EPA REG No.; 100-1055;
PRODUCT NAME: Weather Block Rodenticide Bait with Bitrex ; COMPANY NAME: Syngenta Crop Protection, Inc.; MRID # : 440634-01, -02, -03, and 455758-01; Action Code: 674

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

Paul Horng

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., submitted the product chemistry data in MRIDs # 440634-01, -02, -03 and 455758-01; the Confidential Statement of Formula (CSF), a basic formulation dated 14/AUG/01; and a draft label received by the Agency on 16/AUG/01; requesting for reregistration of the end-use product, Weather Block Rodenticide Bait with Bitrex, EPA Reg. No. 100-1055. The product was originally owned by Zeneca Ag Products. EPA Registration Number was 10182-339. It was acquired by Syngenta Crop Protection, Inc. on 23/FEB/2001.

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 Ingredient (TGAI) chlorophacinone, diphacinone, brodifacoum, bromadiolone, and bromethalin. The Agency has completed the review and determined that these chemicals, labeled and used as specified in this RED, will not pose unreasonable risk or adverse effects to humans or the environment. Therefore, the Agency concludes that products containing brodifacoum, bromethalin, bromadiolone, chlorophacinone, and diphacinone and its sodium salts are eligible for reregistration. The Agency has also determined that field bait uses containing more than 0.0050% chlorophacinone and diphacinone and its sodium salt are eligible for reregistration. The Agency has also determined that all used pival and its sodium salts are ineligible for reregistration and are to remain suspended. The generic data bases of product chemistry supporting the reregistration of brodifacoum, bromethalin, bromadiolone, chlorophacinone, and diphacinone have been determined to be substantially complete. No data gap was cited.
- 2(a). Except for the data gaps noted in Finding # 2(b), the submitted data in MRID # 445758-01 satisfy the data requirement for the Guideline 61-2b (830-1650, Description of Manufacturing Process). The submitted data in MRID # 440634-03 support the data requirement for the Guideline 62-3 (Enforcement Analytical Method). The submitted data in MRID # 440634-01 satisfy the remaining product chemistry data requirements for the Guidelines Series 61, 62, and 63.
- 2(b). The data in MRID # 440634-02, which provided only six-week of storage stability and corrosion characteristics data. It is not sufficient to satisfy the data requirements for the Guidelines 63-17 (830-6317,

Storage Stability), and 63-20 (830-6320, Corrosion Characteristics). The registrant must provide one-year of storage stability data of the active ingredient in the product and corrosion characteristics data of the product to the container.

3. The submitted CSF, a basic formulation dated 14/AUG/01, has been filled out completely and correctly. The nominal concentration, upper limit, and lower limit of the active and inert ingredients in the CSF comply with the requirement of 40 CFR 158.175. All ingredients claimed in the CSF have been cleared for use in pesticide formulation. The CSF is acceptable.
4. 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 the 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 REDs have 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 end-use product, Weather Blok Rodenticide Bait with Bitrex, EPA Reg. No. 100-1055.

Group B: Series 830- Physical and Chemical Properties (40 CFR 158.190)
MRID # 440634-01

GUIDELINE REFERENCE NO.(GRN)/TITLE 830-	VALUE OR QUALITATIVE DESCRIPTION/ METHODS USED WHERE APPLICABLE AND REFERENCES	Comments
-6302 Color.	Blue color (7.85 B), Munsell value of 2 and chroma of 5.0	A
-6303 Physical State.	Solid at 20°C.	A
-6304 Odor.	Aromatic or garlic-like.	NR
-6314 Oxidation/ Reduction Action.	N/A, none of the components used in the formulation are known to be oxidizing or reducing agents.	N/A
-6315 Flammability.	N/A, the product contains no combustible liquid.	N/A
-6316 Explodability.	N/A, the product contains no explosive agents. No explosive potential is anticipated.	N/A
-6317 Storage Stability.	The test substance approximately 8 pounds was stored in its original container (12.5 pound plastic pail). It was stored in the Cole Grower Warehouse, Madison, Wisconsin under normal heated warehouse temperature and humidity conditions for approximately six weeks. The mean concentration of the active ingredient in the product at initial and six weeks after storage was found to be 0.0053 and 0.0050%, respectively. The registrant submitted six-week storage stability data, which is not sufficient to satisfy the data requirement. MRID # 440634-02.	One-year storage stability data are required.
-6319 Miscibility.	N/A, the product is solid and not to be diluted with water.	N/A
-6320 Corrosion Characteristics	Six-week corrosion data are not sufficient to satisfy the data requirement. MRID # 440634-02.	One- year data are required.
-7000 pH.	N/A, the active ingredient (0.005%) is not water soluble. It is formulated with 99.995% solid material [REDACTED]	N/A
-7100 Viscosity.	N/A, the product is not a liquid.	N/A
-7300 Bulk Density	1.20 g/mL at 20°C.	A

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

INERT INGREDIENT INFORMATION IS NOT INCLUDED

Page _____ is not included in this copy.

Pages 4 through 5 are not included in this copy.

The material not included contains the following type of information:

 X Identity of product inert ingredients.

 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.
