US EPA ARCHIVE DOCUMENT

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

October 16, 2002

MEMORANDUM:

Subject: EPA Reg. No.: 100-1056/HAVOC Rodenticide Bait Pack Pellets w/Bitrex
DP Barcode: D285919
Case No.: 2760

From: Marianne Lewis, Biologist
Product Reregistration Branch
Special Review and Reregistration Division (7508C)

Marianne Lewis 10/16/02

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

Applicant: Syngenta Crop Protection, Inc.
P.O. Box 18300
Greensboro, NC 27419

FORMULATION FROM EPA Reg. No. 100-1056 LABEL:

	% by wt.
Active Ingredient(s):	
Brodifacoum: 3-[3-(4'-bromo-[1,1'-biphenyl]-4-yl)-1,2,3,4-tetrahydro-1-napthalenyl]-4-hydroxy-2H-1-benzopyran-2-one	0.005%
Inert Ingredient(s):	99.995%
Total	100.000%

BACKGROUND: In the 8 month response to the Rodenticide Cluster RED, the registrant is citing acute toxicity studies and an attrition study to support the reregistration of their product, EPA Reg. No. 100-1056. The MRID's were as follows: 449837-01 (81-1), 457189-01 (81-2), 457607-01 (attrition study for 81-3), 445979-01 (81-4), 440217-03 (81-5) and 440217-04 (81-6). Five (81-1, 81-2, 81-4, 81-5, 81-6) of the studies were conducted by Zeneca Central Toxicology Laboratory in Cheshire, UK. The test material used in four (81-2, 81-4, 81-5, 81-6) of these studies was Brodifacoum Formulation Concentration (0.25% w/w), EPA Reg. No. 100-986. The material used in the acute oral study (81-1) was EPA Reg. No. 100-1052 which is listed in the RED along with the subject product. The attrition study for 81-3 was conducted by HACCO Analytical Laboratory. The test material used was EPA Reg. No. 100-1057 which is listed in Batch 2 of the RED along with the subject product.

The acute oral study (81-1) was reviewed and found to be acceptable by PRB/SRRD on 10/16/02. The acute dermal study (81-2) is being reviewed currently and has been found to be acceptable by PRB/SRRD. The registrant submitted an attrition study, at the request of the Agency, to support their acute inhalation study waiver. This study was reviewed by PRB/SRRD and has been found to be acceptable to support the waiver request. Therefore, based on the attrition study results the subject product will be assigned Toxicity Category IV for the acute inhalation study (81-3) requirement. The primary goal of the Agency is to protect the public. Therefore, the Agency wishes to assure the registrant that all companies and products being reregistered by PRB/SRRD are held to the same high scientific standards.

The primary eye irritation study (81-4) cited was reviewed and found to be unacceptable by PRB/SRRD on 3/28/02. However, based on information contained in the study and the open literature the Agency will assign the subject product Toxicity Category IV.

The primary skin irritation study (81-5) cited was reviewed and found to be unacceptable by PRB/SRRD on 3/28/02. However, based on information contained in the study, open literature, and MSDS' the Agency will assign the subject product Toxicity Category III.

The skin sensitization study (81-6) cited was reviewed and found to be unacceptable by PRB/SRRD on 3/28/02. However, based on information contained in the open literature and MSDS' the Agency will classify the subject product as a non sensitizer.

RECOMMENDATIONS:

- The acute oral (81-1) and acute dermal (81-2) studies cited are acceptable to support the reregistration of EPA Reg. No. 100-1056.
- The acute inhalation (81-3) study requirement is waived for the subject product and assigned Toxicity Category IV.
- The primary eye irritation (81-4) study cited is unacceptable. However, the Agency will assign Toxicity Category IV for this requirement. A new study is not needed.
- The primary skin irritation (81-5) study cited is unacceptable. However, the Agency will assign Toxicity Category III for this requirement. A new study is not needed.

- The skin sensitization (81-6) study cited is unacceptable. However, the Agency will classify the subject product as a non sensitizer. A new study is not needed.

The acute toxicity profile for EPA Reg. No. 100-1056 is currently:

Acute Oral	IV	Cited/Acceptable
Acute Dermal	III	Cited/Acceptable
Acute Inhalation	IV	Cited/Waived
Primary Eye	IV	Cited/Unacceptable
Primary Dermal	III	Cited/Unacceptable
Skin Sensitization	non sensitizer	Cited/Unacceptable

NOTE: The acute toxicity requirements have been satisfied for the subject product.

LABELING: HOMEOWNER

ID #: 000100-01056 HAVOC RODENTICIDE BAIT PACK PELLETS WITH BITREX

SIGNAL WORD: CAUTION

HAZARDS TO HUMANS AND DOMESTIC ANIMALS:

Harmful if swallowed. Harmful if absorbed through skin. Avoid contact with skin, eyes, or clothing. Wear chemical resistant gloves (such as or made out of any waterproof material, selection category A). Wash thoroughly with soap and water after handling. Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

FIRST AID:

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

Note to CRM/PM/Registrant:

The proposed label should contain a Note to Physician which addresses the presence of an anticoagulant. The following statements are some suggested types of information that could be included, if applicable, in the Note to Physicians:

- technical information on symptomatology;
- use of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological effects of the pesticide;
- company telephone number to specific medical personnel who can provide specialized medical advice.

LABELING: COMMERICAL

ID #: 000100-01056 HAVOC RODENTICIDE BAIT PACK PELLETS WITH BITREX

SIGNAL WORD: CAUTION

HAZARDS TO HUMANS AND DOMESTIC ANIMALS:

Harmful if swallowed. Harmful if absorbed through skin. Avoid contact with skin, eyes, or clothing. Wear long-sleeved shirt and long pants, shoes and socks, and chemical resistant gloves (such as or made out of any waterproof material, selection category A). Wash thoroughly with soap and water after handling.

FIRST AID:

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

USER SAFETY RECOMMENDATIONS:

Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Note to CRM/PM/Registrant:

The proposed label should contain a Note to Physician which addresses the presence of an anticoagulant. The following statements are some suggested types of information that could be included, if applicable, in the Note to Physicians:

- technical information on symptomatology;
- use of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological effects of the pesticide;
- company telephone number to specific medical personnel who can provide specialized medical advice.