

US EPA ARCHIVE DOCUMENT



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

August 7, 2002

MEMORANDUM:

Subject: EPA Reg. No.: 100-987/Brodifacoum Technical
DP Barcode: D283985
Case No.: 2755

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

Marianne Lewis 8/8/02

To: Venus Eagle-Kunst, 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. 100-987 LABEL:

	<u>% by wt.</u>
<u>Active Ingredient(s):</u>	
Brodifacoum 3-[3-(4"-bromo-[1,1'biphenyl]-4-yl)-1,2,3,4- tetrahydro-1-naphthalenyl]-4-hydroxy-2H-1-benzopyran-2-one	90.0%
<u>Inert Ingredient(s):</u>	<u>10.0%</u>
Total	100.0%

BACKGROUND: In the 8 month response to the Rodenticide RED, the registrant is citing four of the acute toxicity studies done on the technical found in the RED and is requesting two waivers to support the reregistration of EPA Reg. No. 100-987. The MRID's are as follows: 426875-01 (81-1), 422321-01 (81-2), 431105-01 (81-3), and 66938 (81-4). These studies were reviewed by TRB/RD and found to be acceptable.

The registrant is requesting that the Agency waive the primary dermal irritation study and the skin sensitization study. The Agency will grant the waivers due to the highly toxic nature of this product.

The Agency looked at the corrosive and irritating properties as well as the toxic nature of the subject product and agrees with the assessment found in the RED that mortality is a high probability if the material is absorbed through the ocular exposure route. Therefore, the Agency will reclassify the primary eye irritation toxicity category to a Toxicity Category I.

The primary skin irritation study will be classified as Toxicity Category I based on the highly toxic nature of the subject product via the acute dermal route. The Agency acknowledges that this probably won't irritate or corrode the skin however it will in all likelihood cause death.

The skin sensitization study will be waived due to the highly toxic nature of the subject product.

RECOMMENDATIONS:

- The four (81-1, 81-2, 81-3, 81-4) acute toxicity studies cited are acceptable to support the reregistration of EPA Reg. No. 100-987. However, the primary eye irritation study (81-4) will be reclassified to Toxicity Category I..
- The primary skin irritation study (81-5) waiver request is granted. The subject product will be assigned Toxicity Category I for this requirement.
- The skin sensitization study (81-6) waiver request is granted.

The acute toxicity profile for EPA Reg. No. 100-987 is currently:

Acute Oral	I	Cited/Acceptable
Acute Dermal	I	Cited/Acceptable
Acute Inhalation	I	Cited/Acceptable
Primary Eye	I	Cited/Reclassified
Primary Dermal	I	Waived
Skin Sensitization		Waived

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

LABELING:

ID #: 000100-00987 **BRODIFACOUM TECHNICAL**

SIGNAL WORD: **DANGER**

POISON (SKULL & CROSSBONES symbol)

HAZARDS TO HUMANS AND DOMESTIC ANIMALS*:

Fatal if absorbed through skin. Fatal if inhaled. Fatal if swallowed. Fatal if in eyes. Do not get in eyes, on skin, or on clothing. Do not breath spray mist. Wash thoroughly with soap and water after handling. Remove and wash contaminated clothing before reuse. Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

* The designation of Personal Protective Equipment (PPE) for manufacturing use products does not fall under the jurisdiction of EPA, therefore, PPE has not been specified for this product.

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 INHALED: Move person to fresh air. If person is not breathing, call 911 or ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

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 category I for oral toxicity, dermal toxicity, inhalation toxicity, primary eye irritation, primary skin irritation and 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.