



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

January 21, 2000

MEMORANDUM:

Subject: EPA Reg. No.: 10182-29/Brodifacoum Technical
Case No.: 2760

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

Marianne Lewis 2/15/00
MJP

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

Applicant: ZENECA Inc.
1800 Concord Pike
Wilmington, DE 19897

FORMULATION FROM EPA Reg. No. 10182-29 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 Cluster RED, the registrant is requesting to waive the acute inhalation study (81-3) for their product, EPA Reg. No.10182-29. In their waiver request, the registrant states that they conducted a trial run to “generate the test material, using the pelleted formulation, which met the minimum particle size distribution requirement in order to conduct an acute inhalation study according to EPA test protocol guidelines.” However, the test material that was milled was a solid bait product which contained only 0.005 % of the active ingredient. The trial run that was conducted on this bait product can not be used as a representative study to demonstrate the particle size of the technical Brodifacoum. However, based on information available to the Agency, the acute inhalation study will be waived for the subject product and the product, EPA Reg. No. 10182-29, will be classified as Toxicity Category I.

RECOMMENDATIONS:

- The acute inhalation study (81-3) requirement for the subject product has been waived. EPA Reg. No. 10182-29 will be classified as Toxicity Category I for the acute inhalation requirement.

The acute toxicity profile for EPA Reg. No. 10182-29 is currently:

Acute Oral		Data Needed
Acute Dermal		Data Needed
Acute Inhalation	I	Waived
Primary Eye		Data Needed
Primary Dermal		Data Needed
Skin Sensitization		Data Needed

NOTE: The labeling will be completed when all of the required information is received.