



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

January 21, 2000

MEMORANDUM:

Subject: EPA Reg. No.: 10182-334/Talon-G Rodenticide Bait Pack (Mini-Pellets)
EPA Reg. No.: 10182-335/Talon-G Rodenticide Bait Pack Pellets w/Bitrex
EPA Reg. No.: 10182-336/Brodifacoum Rodenticide Pellets w/Bitrex
EPA Reg. No.: 10182-337/HAVOC Rodenticide Bait Pack Pellets w/Bitrex
EPA Reg. No.: 10182-338/HAVOC Rodenticide Bait Pack Mini-Pellets
EPA Reg. No.: 10182-341/Talon-G Rodenticide Mini-Pellets w/Bitrex
Case No.: 2760

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

Marianne Lewis 2/15/00
MPL

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. 10182-334 LABEL:

Active Ingredient(s):

Brodifacoum: 3-[3-(4'-bromo-[1,1'-biphenyl]-4-yl)-1,2,3,4-tetrahydro-
1-naphthalenyl]-4-hydroxy-2H-1-benzopyran-2-one 0.005 %

Inert Ingredient(s): 99.995 %

Total 100.000 %

FORMULATION FROM EPA Reg. No. 10182-335 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 %

FORMULATION FROM EPA Reg. No. 10182-336 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 %

FORMULATION FROM EPA Reg. No. 10182-337 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 %

FORMULATION FROM EPA Reg. No. 10182-338 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 %

FORMULATION FROM EPA Reg. No. 10182-341 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 requesting to waive the acute inhalation study (81-3) for the following products: EPA Reg. Nos.: 10182-334, 10182-335, 10182-336, 10182-337, 10182-338, and 10182-341. The registrant 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." The laboratory was unable to generate the appropriate percentage of particles in the acceptable size range of 1- 4 μ m. The registrant was contacted and an inquiry was made as to how long the test material was milled/ground. Based on the registrant's reply, it appears that the milling was conducted over the course of one business day, or approximately 8 hours. The Agency prefers that any test material that does not easily produce the appropriately sized particles, be milled or ground (by air mill, ball mill, hammer mill, utilization of dry ice) for 24 hours if necessary. If the laboratory can demonstrate that the particle size has reached a plateau prior to 24 hours, then no further milling is needed.

Since the laboratory only attempted to mill the test material for approximately 8 hours, the Agency can not conclude that respirable particles could not be generated from this product. However, based on information available to the Agency, the acute inhalation study will be waived for the subject products and all will be classified as Toxicity Category I.

RECOMMENDATIONS:

- The acute inhalation study (81-3) requirement for the subject products has been waived. All subject products will be classified as Toxicity Category I.

The acute toxicity profile for EPA Reg. No. 10182-334 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

The acute toxicity profile for EPA Reg. No. 10182-335 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

The acute toxicity profile for EPA Reg. No. 10182-336 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

The acute toxicity profile for EPA Reg. No. 10182-337 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

The acute toxicity profile for EPA Reg. No. 10182-338 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

The acute toxicity profile for EPA Reg. No. 10182-341 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.