US EPA ARCHIVE DOCUMENT

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DATE: October 4, 1979

SUBJECT: EPA File Symbols 10182-EN/EA/ER/EL/EU/EG/EE. Products Containing 0.005% Brodifacoum.

FROM: John Doherty 10/5/79 Toxicology Branch/HED (TS-769)

Caswell #114AAA

TO: Daniel Peacock
Product Manager Team #16/RD (TS-767)

Action Requested: Assign signal word and advise on precautionary labelling.

These seven products are various formulations of Brodifacoum baits and pellets either in special trays or as hard pellets. All are of the following composition:

Active Ingredient	
Brodifacoum	0.005%
Inert	99.995%

The physical nature of these formulated products precluded adequate determination of the acute oral or dermal LD50, or the inhalation LC50.

Extrapolation of data with technical brodifacoum indicates that this dilute concentration of active ingredient would have a toxicity category III classification. (See Summary Table attached).

Conclusion:

1. These products should have the signal word "CAUTION."
2. These products should be classified for "General Use".
3. Toxicology Branch recommends that the precautionary labelling statement be altered to include the instruction "Do not store unused product in food storage areas" to all of these products.

Remarks:

1. The product 10182-EA contains on the front label "Kills anticoagulant-resistant rats and mice". This statement should be altered or removed because it may confuse a physician treating a possible poisoning victim. Brodifacoum is in fact an anticoagulant.
2. These products should be packaged so as to minimize the possibility that they will be mistaken for human food. Child resistant packaging is recommended.

SUMMARY TABLE: ACUTE TOXICITY OF 0.005% BRODIFACOUM

Test	Results	TOX Cat.	Core Classification
Acute Oral LD 50, rats	- (1)	(IV)	SUPPLEMENTARY
Acute Dermal LD 50, rabbits	>500 mg/kg (2)	(IV)	SUPPLEMENTARY
Acute Inhalation LC 50, rats	>.0595 mg/li/4 hr(3)	(IV)	SUPPLEMENTARY
Dermal Irritation, rabbits	Not irritating	III	MINIMUM
Eye Irritation, rabbits	1 rabbit developed corneal opacity (considered incidental)	III	MINIMUM

(1) No acute oral LD50 could be successfully determined because of the nature of this product. Extrapolation from the technical LD50 data (0.35 mg/kg, Brodifacoum) suggests that the LD50 will be 7.6 gm/kg or Toxicity Category IV.

(2) No higher doses of test material could be applied. Extrapolation from the technical LD50 data (about 2.5 mg/kg) suggests that the LD50 will be 50 gm/kg or Toxicity Category IV.

(3) This was the highest achievable concentration. The nature of this product precludes volatization.