4.25-94

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM:

Subject: EPA Reg. No./File Symbol: 4581-292 / Penncap M

From: Ian Blackwell, Biologist IDB 4/22/94
Precautionary Review Section
Registration Support Branch
Registration Division (7505W)

To: Dennis Edwards, PM 19
Insecticide-Rodenticide Branch
Registration Division (75O5C)

Thru: Thomas C. Ellwanger, Section Head Thomas C. Ellwanger for 4-25-94
Precautionary Review Section
Registration Support Branch
Registration Division (7505W)

Applicant: Elf Atochem North America, Inc.
Three Parkway
Philadelphia, PA 19102

FORMULATION FROM LABEL:

Active Ingredient(s)::	% by wt.
O,O-Dimethyl O-P-nitrophenyl phosporothioate	20.9
Related isomers	1.1
Inert Ingredient(s):	78.0
Total:	100.00%

BACKGROUND: Elf Atochem North America, Inc., has submitted a request for the waiver of the acute inhalation toxicity study for their product "Penncap M", reg. no. 4581-282. Acute toxicity studies of this product were reviewed by PRS on 9/23/91 and 1/21/94. The results of the last review were:

acute oral toxicity		supplementary
acute dermal toxicity	III	minimum
acute inhalation toxicity	REQUESTED	
primary eye irritation	IV	minimum
primary skin irritation	IV	minimum
dermal sensitization	sensitizer	minimum

The registrant wishes to have the acute inhalation toxicity study waived for the following reasons:

1. The product is a microencapsulated formulation consisting of many capsules, approximately 88% of which are above 10 microns in diameter. The larger particles would clog the spraying devices set to produce particles below 4 microns in size. If the pressure of the sprayer is increased enough to force the larger particles through the spraying apparatus, the larger particles will simply be crushed releasing their contents. With such a large percentage of crushed particles, the study would not be representative of the normal product formulation.

2. The product is intended to be sprayed so that small particles that would drift would not be formed. The large particles will drop rapidly. Also, the particles agglomerate and it is very difficult to get them to separate out by size.

RECOMMENDATIONS:

1. PRS denies the waiver for the acute inhalation toxicity study of reg. no. 4581-292. According to the 8/24/93 Thomas Ellwanger Acute Toxicity Waiver Guidance Document, in order for PRS to waive the acute toxicity study for this product the lab would have to have attempted to crush or fracture the capsules with a high speed homogenizer. There are several criteria that must be met in order to grant an inhalation toxicity data waiver. Please forward the attached Thomas Ellwanger memo to the registrant. Unless the registrant can meet the waiver requirements in the attached memo, the lab must conduct the acute inhalation toxicity study with a sample of the test material prepared such that the study can be conducted.

2. The registrant must submit an acute oral toxicity study to support the registration product.

The acute toxicity profile for reg. no. 4581-292 is currently:

acute oral toxicity		supplementary
acute dermal toxicity	III	minimum
acute inhalation toxicity	REQUESTED	
primary eye irritation	IV	minimum
primary skin irritation	IV	minimum
dermal sensitization	sensitizer	minimum

LABELING:

1. The signal word is "CAUTION", based on the results of the acute toxicity studies. It should be noted, however, that the acute toxicity profile for this product is incomplete.

2. Based on the current acute toxicity profile, the precautionary statements should state:

   "Harmful if absorbed through skin. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals."

   At this time, PRS in unable to comment on precautionary statements concerning oral or inhalation exposure.

3. The statements of practical treatment should state:

   "**If on skin**: Wash with plenty of soap and water. Get medical attention."

   The label submitted for the 1/21/94 review of reg. no. 4581-292 contains a toxicity category I/II statement of practical treatment for ocular exposure. Based on the results of the previously submitted primary eye irritation study, a statement of practical treatment for ocular exposure is not required. However, PRS will allow the registrant to retain this ocular exposure statement if so desired.

4. The labeling recommendations for reg. no. 4581-292, including the signal word, statements of practical treatment and precautionary statements may require revision upon the submission of the outstanding acute oral and inhalation toxicity studies.