2-3-81

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DATE: February 3, 1981

SUBJECT: VC17m Antifouling
EPA File Symbol 45168-R

FROM: Sherell A. Sterling
FHB/TSS

TO: Richard Mountfort
Product Manager (23)

Applicant: Extensor AB
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Active Ingredient:
Copper as metallic.....?
Inert Ingredients.....?

Background: Acute Oral, Acute Dermal, Acute Inhalation, Eye and Skin Irritation studies were submitted for VC17m Antifouling. Studies were conducted by Tox Monitor Laboratories, Inc. of Melrose Park, Illinois. The "alternate" method of support was chosen.

Recommendations:

1. The Acute Oral study is adequate and acceptable support for the conditional registration of this product. However, the following points must be noted for future studies:

   a) Equal numbers of males and females must be tested at each dosage level.

   b) Response data and any required calculations must be reported separately for males, females.

2. The Acute Dermal study is considered adequate and acceptable for the conditional registration of this product. Please note the following for future reference:

   a) Equal numbers of males and females must be tested at each dosage level.

   b) Response data and any required calculations must be reported separately for males and females.

c) The highest required dosage is 2 g/kg, all animals with abraded skin sites.

3. The Acute Inhalation study is considered Core Supplementary Data and, as such, is not sufficient to support the conditional registration of this product. Please note the following problems encountered in evaluating this study:

a) Data were based on nominal concentrations, not actual concentrations. Since the toxicity scoring system in 40 CFR 162.10 is based on actual concentration, correct toxicity category could not be assigned.

b) The highest required dosage level is 5 mg/l for four hours duration, actual concentration.

c) More in-depth descriptions must be reported for chamber design, operation and monitoring equipment used.

For a more complete outline of Acute Inhalation reporting needs, please consult §163.81-3 of the enclosed "Proposed Guidelines for Human Hazard Evaluation."

4. The Eye Irritation study is adequate and acceptable support for the conditional registration of this product. For further studies, please note the following comments:

a) An additional group (minimum of 3 animals) must be treated and subsequently subjected to an eyewash.

b) Complete scores according to Draize method - including area of corneal involvement and discharge - must be submitted for each animal.

Please see §163.81-4 of the"Proposed Guidelines" for further information.

5. The Primary Skin Irritation study is adequate and acceptable for conditional registration purposes. However, please note the following:

a) There must be four sites, 2 abraded and 2 intact, tested on each animal.

6. Please note that the Dermal Sensitization study is required; however, FHB/TSS is of the opinion that the study is not necessary at this time.

7. FHB/TSS objects to the conditional registration of this product under the "alternate" method of support until an acceptable Acute Inhalation study is submitted.

Labeling Recommendation:

1. Based on the Eye Irritation study, the appropriate signal word is DANGER. This signal word must appear on the front panel of the labeling.

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2. The appropriate placement of the statement "Keep out of reach of children" is above the signal word on the front panel.

3. "See back panel for other caution" must be replaced with the statement "See back panel for additional precautionary statements."

4. Under "Important properties for you," number 1 delete the word poisonous from the first and last lines.

5. Delete number 5 under "Important properties for you." The statement which must be deleted reads "You get a first rate bottom coat free from all fat soluble life endangering poison."

6. The back panel precautionary statements (statements in the box) must be revised as follows. The appropriate placement of this section is before the "Directions for Use."

   a) The heading "PRECAUTIONARY STATEMENTS" must appear first.

   b) Following the "PRECAUTIONARY STATEMENTS" heading, the subheading "Hazards to Humans and Domestic Animals" must appear.

   c) The "Hazards to Humans and Domestic Animals" section must contain the following:

      "DANGER. Corrosive, causes eye damage and skin irritation. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Wash hands thoroughly after using. Use with adequate ventilation."

   d) A "Statement of Practical Treatment" must be included on the labeling. This section may appear beneath the "Hazards to Humans and Domestic Animals" section or on the front panel with other front panel precautionary statements. Following the subheading "Practical Treatment" please include the following or similar statements:

      "<u>If in eyes</u>: Flush with water for 15 minutes. Get medical attention if irritation persists.

      <u>If on skin</u>: Wash with plenty of soap and water. Get medical attention if irritation persists."

e) Following the "Hazards to Humans and Domestic Animals" section, the subheading "Environmental Hazards" subheading must appear with the following statements:

> "Do not apply directly to lakes, streams or ponds. Do not contaminate water by cleaning of equipment or disposal of wastes."

f) Under "Physical or Chemical Hazards" subheading, the following or similar statement must appear:

> "Do not store near heat or open flame."

7. A "Storage and Disposal" statement must appear on the labeling. The appropriate place for this statement is at the end of the "Directions for Use" section. Please see the enclosed sheets for the "Storage and Disposal" statements required for your product.

8. The misuse statement "It is a violation of federal law to use this product in a manner ~~be~~ inconsistent with its labeling" must appear on the labeling. The appropriate placement of this statement is preceding the "Directions for Use."

9. Enclosed is a copy of the format labeling which may be useful in preparing label revisions.

Review:

1. Acute Oral Toxicity; Tox Monitor #TM 80-246A; August 18, 1980; Acc. No. 243712.

   Procedure: Eleven Sprague-Dawley rats, sex unknown, each received an oral dosage of "VC 17-m." Dosage level was 5 ml/kg (7.336g/kg) for each animal. Animals were observed for 14 days. Necropsies were performed on all survivors.

   Results: All animals gained weight; all animals survived. The LD_{50} > 5ml/kg (7.336 g/kg). Observations reported were prostration, slowed respiratory rate for approximately 3 hours post-dosing. Necropsy revealed: organs of thorax and abdomen appeared normal.

   Study Classification: Core Mininmum Data. Sex of animals was not reported.

   Toxicity Category: IV - CAUTION
   Due to the high dosage rate, even if animals of only one sex were tested any variation between the sexes has a large probability or being no worse than Toxicity Category IV.

2. Acute Dermal Toxicity; Tox Monitor #TM 80-246A; August 18, 1980; Acc. No. 243712.

   Procedure: Six New Zealand white rabbits each received dosages of 20 ml/kg (29.35 g/kg) of "VC17-m" at an intact site. Exposure was for 24 hours under occulusive wrap. Animals were observed for 14 days; afterwards all animals received necropsies.

   Results: All animals survived; all gained weight. Animals appeared normal throughout study. LD_{50} > 20 ml/kg (≈29.35 g/kg).

   Study Classification: Core Minimum Data. Sex of animals was not reported. Highest dosage necessary to test is 2 g/kg, all animals with abraded skin.

   Toxicity Category: ~~III~~ IV - CAUTION

3. Acute Inhalation Toxicity; Tox Monitor # T80 - 246A; August 18, 1980; Acc. No. 243712.

   Procedure: Ten Sprague-Dawley rats (5♂, 5♀) in separate cages were each exposed to 20 mg/l (nominal concentration) of "VC17-m." Exposure was for one hour in plexiglass cages with 355.5 ℓ^3 capacity. Animals were observed for 14 days post-treatment; all were subjected to necropsies.

   Results: All animals survived; all gained weight during study. Observation of animals revealed all animals normal throughout study. Necropsy revealed organs of thorax and abdomen to be normal.

Study Classification: Core Supplementary Data. Atmospheric concentration was not measured.

4. Eye Irritation; Tox Moitor #TM 80-246A; August 18, 1980; Acc. No. 243712.

Procedure: 0.1 ml of "VC17-m" was applied into one eye of each of six rabbits. Eyes were observed at 24,48,72 hours post-instillation for irritation.

Results: At 24 hours, cornea showed 5/6=1; conjunctival erythema in 6/6=2 and conjunctival chemosis in 5/6=1, 1/6=2. By day 7 irritation observed was corneal in 1/6=1 and conjunctival erythema in 3/6=1.

Study Classification: Core Minimum Data. A concurrent study of three eyes which were treated and subsequently rinsed must be run. Complete scores - including area of corneal involvement and discharge - must be reported according to Draize's method.

Toxicity Category: I - DANGER.

5. Primary Skin Irritation; Tox Monitor #TM 80 - 246A; August 18, 1980, Acc. No. 243712.

Procedure: Six albino rabbits each received 0.5 ml of "VC17m" at each of 2 sites (1 intact, 1 abraded). Exposure was for 24 hours under occlusive wrap. Eye were examined at 24, 72 hours.

Results: At 24 hours intact sites all showed very slight erythema and slight edema; abraded sites exhibited the same effects. By 72 hours, intact sites all showed edema; abraded sites exhibited the same effects. The Primary Irritation Index is 3.0.

Study Calssification: Core Minimum Data. Test must include 4 sites (2I and 2A) per animal.

Toxicity Category: III - CAUTION

well-defined erythema and very slight

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