



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

004672

MEMORANDUM

Date: December 1, 1982

Subject: EPA File Symbol: 476-EERA  
Eptam Plus 6-E

From: Deloris F. Graham  
FHB/TSS

*DFG 12/3/82*  
*E 12/8/82*

To: Robert Taylor  
Product Manager (25)

Applicant: Stauffer Chemical Company  
1200 South 47th Street  
Richmond, California 94804

*See serial file 7*

Active Ingredients:

*476* S-ethyl dipropylthiocarbamate.....73.4%  
Inert Ingredients.....26.6%

Background: Submitted Acute Oral, Acute Dermal, Eye Irritation and Primary Dermal Irritation studies. Studies conducted by Stauffer Chemical Company. Data under accession number 248776. Method of support not indicated.

Recommendation:

- (1) FHB/TSS finds these data acceptable to support conditional registration of this product. However, for future submissions please note:
  - (a) In the Eye Irritation Study, individual scoring of corneal opacity, iris irritation, conjunctive redness, chemosis and discharge for each animal must be submitted.
- (2) An Acute Inhalation Study was not submitted and one must be submitted and/or cited.
- (3) The appropriate signal word is *WARNING*

Label:

- (1) The statement "Do not contaminate food or feed" must be deleted from precautionary statements and placed under "Directions For Use."
- (2) The statement "Do not contaminate water by cleaning of equipment or disposal of wastes" must be deleted from "Environmental Hazards" and placed under "Storage and Disposal."

Review:

- (1) Acute Oral Toxicity Study: Stauffer; Report #T-10911; May 12, 1982.

Procedure: 3 groups, consisting of 10M rats each, received one of the following doses: 1000, 1259 and 1585 mg/kg. Observations made for 14 days after treatment. Necropsy performed on all animals. Twenty male rats were treated with water and served as controls.

Results: At 1000 mg/kg, 1/10 died; at 1259 mg/kg, 4/10 died; at 1585 mg/kg, 8/10 died. Clinical signs observed included depression, prostration, ataxia, salivation, lacrimation, diuresis, ptosis, dyspnea, red facial stains, diarrhea, tremors, hypersensitivity, aggressive behavior, piloerection and vocalization. Necropsy revealed reddened lungs, pale tan mottled livers, reddened gastrointestinal mucosa and very pale or slightly purple testes, dark red fluid in bladder, pale testes, black solid material in intestines. No abnormalities noted in control animals. LD<sub>50</sub> was 1326 mg/kg with confidence limits between 1162 and 1514 mg/kg.

Study Classification: Core Guideline Data.

Toxicity Category: III - CAUTION

- (2) Acute Oral Toxicity Study: Stauffer; Report #T-10911; May 12, 1982.

Procedure: 5 groups, consisting of 10F rats each, received one of the following doses: 750, 794, 891\*, 1000, and 1259 mg/kg. Observations made for 14 days after treatment. Necropsy performed on all animals. Thirty female rats were treated with water and served as vehicle controls.

\*Group dosed at 89 mg/kg consisted of 20F rats.

Results: At 794 mg/kg, 3/10 died; at 89 mg/kg, 5/20 F died; at 1000 mg/kg, 5/10 died; at 1259 mg/kg, 8/10 died. Clinical signs observed included depression, vocalization, piloerection, hypersensitivity, tremors, convulsions, lacrimation, salivation, a hunched posture, red facial stains, ano-genital stains, ataxia, prostration, hypersensitivity to touch and sound, ptosis, diuresis, diarrhea, dyspnea, and cannibalistic

behavior. Necropsy revealed pale tan livers and kidneys, reddened lungs, dark-edged livers, reddened GI mucosa, black spleen, pale pink thymus in one rat, intestines filled with a black fluid; at highest dose all animals found in a state of rigor. LD50 was 1025 mg/kg with confidence limits between (908 and 1157 mg/kg). No abnormalities in control group.

Study Classification: Core Guideline Data.

Toxicity Category: III - CAUTION

- (3) Acute Dermal Toxicity Study: Stauffer; Report #T-10911; May 12, 1982.

Procedure: 5M and 5F rabbits received a single dermal application of 2000 mg/kg of the test material under occlusive wrap for 24 hour exposure. The skin was abraded on half the animals and left intact on the others. At the end of the 24-hour exposure period the binder material was removed and the skin was inspected for irritation and rewrapped in a gauze binder. Three days later, this gauze binder was removed. The animals were observed for a 14 day period following the initial treatment. Necropsy performed on all animals. A group of 2M and 2F rabbits were untreated and served as controls.

Results: No mortalities. Mild to moderate erythema and edema. No abnormalities at necropsy. LD<sub>50</sub> greater than 2000 mg/kg.

Study Classification: Core Guideline Data.

Toxicity Category: III - CAUTION

- (4) Eye Irritation Study: Stauffer Chemical Company; Report #T-10911; May 12, 1982.

Procedure: Nine rabbits received 0.1 ml of the test material in one eye each. The treated eyes of three of the rabbits were washed 20-30 seconds after treatment. Observations made at 24, 48, 72 hours, 4, 7 and 14 days after treatment.

Results: 5/5 animals of the unwashed group had mild corneal opacity, mild iritis, and mild to moderate conjunctive irritation within 24 hours. The iritis had cleared within 48 hours and the opacity and conjunctival irritation within 10 days.

1/3 animals of the washed group had mild conjunctive irritation at 24 hours, but had cleared by 72 hours.

Average total score for 24 hours was 22.8; for 72 hours, 14.6; for 7 days, 3.4; for 14 days, zero.

004672

-4-

Study Classification: Core Minimum Data. Individual scoring of opacity, iris irritation, redness, chemosis and discharge for each animal must be submitted.

Toxicity Category: II - WARNING

- (5) Primary Dermal Irritation Study: Stauffer; Report #T-10911; May 12, 1982.

Procedure: Six rabbits received 0.5 ml of the test material at abraded and intact skin sites per animal under occlusive wrap for 24 hour exposure. Observations were made at 24 and 72 hours after treatment.

Results: Slight to well defined erythema in 6/6 animals (4/6=1, 2/6=2) and slight edema in 6/6 animals (6/6=1) at 24 hours.

At 72 hours, 5/6 slight erythema (5/6=1) and no edema. Primary Irritation Score = 1.5.

Study Classification: Core Guideline Data.

Toxicity Category: IV - CAUTION

## Eptam Science Reviews

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Page \_\_\_\_\_ is not included in this copy.

Pages   5   through  13  are not included in this copy.

The material not included contains the following type of information:

\_\_\_\_\_ Identity of product inert ingredients.

\_\_\_\_\_ Identity of product inert impurities.

\_\_\_\_\_ Description of the product manufacturing process.

\_\_\_\_\_ Description of product quality control procedures.

\_\_\_\_\_ Identity of the source of product ingredients.

\_\_\_\_\_ Sales or other commercial/financial information.

  X   A draft product label.

\_\_\_\_\_ The product confidential statement of formula.

\_\_\_\_\_ Information about a pending registration action

\_\_\_\_\_ FIFRA registration data.

\_\_\_\_\_ The document is a duplicate of page(s) \_\_\_\_\_

\_\_\_\_\_ The document is not responsive to the request.

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The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

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