

Date : March 8, 1983

Subject : EPA File Symbol : 538-RIG
Proterf Fluid Fungicide

005026

From : Deloris F. Graham
JHB/JSS E 3/9/83

To : Kendrick McCoy
Product Manager (21)

Applicant : O. M. Scotts Company
Marysville, Ohio

Active Ingredients :

Thiophanate-methyl, Dimethyl [(1,2-phenylene)
bis (iminocarbonothioyl)] bis [carbamate] . . . 19.65%
(Iproctione), 3-(3,5-Dichlorophenyl)-N-
(1-methyl ethyl)-2,4-dioxo-1-
imidazolidinacarbonylamide . . . 19.65%
Inert Ingredients . . . 60.70%

Background : Submitted Acute Oral, Acute Dermal,
Eye Irritation and Skin Irritation Studies. Studies
conducted by Hazleton Raltech, Inc. Data under
accession number 249 270. Alternate method of
support.

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Recommendation :

US JHB/JSS finds these data acceptable to
support conditional registration of this product.

(2) An Acute Inhalation Study was not
submitted and one must be submitted
and/or cited.

(3) The appropriate signal used is CAUTION.

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Label:

(1) The statement "Do not contaminate feed or feedstuffs. Do not graze treated areas. Do not feed clippings to livestock" must be deleted from precautionary statements and placed ~~in~~ under "Directions For Use".

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Review:

(1) Acute Oral Toxicity Study: Wagleton Raltech, Inc.; RJ Lab. # 987196; September 23, 1980.

Procedure: Five male and five female rats received 5g/kg of the test material orally. Observations were made at 1, 2.5 and 4 hours after treatment, then daily thereafter for 14 days. Necropsy performed on all animals.

Results: No mortalities. Signs observed included diarrhea, soft stools, hyperaesthesia, urine stained abdomen, hypersensitivity to touch, tremors, lacrimation, ataxia, decreased limb tone, piloerection, brownish stained anal and urogenital areas and mucus in one animal. Necropsy revealed - right axillary region - ~~subcutaneous~~ mass, firm, tan, red, lobular; yellowish

nodes appears mildly enlarged; uterus - mild hydrometra. LOSO greater than 5g/Kg for males and females.

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Study Classification: Core Guideline Data.

Toxicity Category: IV - CAUTION

(2) Acute Dermal Toxicity Study: Hazleton Raltech, Inc.; Lab. # 987196; September 9, 1982.

Procedure: Five male and five female rabbits received 2g/Kg of the test material at abraded skin sites under occlusive wrap for 24 hour exposure. Observations were made daily for 14 days after treatment. Necropsy performed on all animals.

Results: No mortalities. Erythema, edema, desquamation and fissuring noted. Necropsy revealed skin in test area reddened and mildly thickened; ~~no~~ no other abnormalities. ~~LOS~~ LOSO greater than 2g/Kg.

Study Classification: Core Guideline Data.

Toxicity Category: III - CAUTION

(3) Eye Irritation Study: Hazleton Raltech, Inc.; Lab. # 987196; September 3, 1982.

Procedure: Nine New Zealand rabbits received 0.1 ml of the test material in one eye each. The treated eyes of three of the rabbits were washed 30 seconds after treatment. Observations were made at 24, 48, 72 and 96 hours and at 7 days.

Results: At 24 hours 2/6 animals of the unwashed group had corneal opacity (75=5); 2/6 iris

irritation ($4/6=1$); $4/6$ and $3/3$ animals of the washed group had redness ($3/6=1.5$, $3/6=2.0$) ($4/3=1.0$, $4/3=1.5$); $4/6+3$ chemosis ($3/6=1.0$, $4/6=1.5$) ($4/3=1.0$) and discharge ($4/6=1$) ($4/3=1$).

at 96 hours $4/6$ had redness ($4/6=1$); no other irritation present. Redness had cleared by day 7.

Study Classification: Core Guideline Data -

Toxicity Category: III - CAUTION

(4) Skin Irritation Study: Hanlepton Raltech, Inc.; RI Lab. # 987196; August 29, 1982.

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

Results: At 24 hours, $4/6$ erythema ($4/6=1.0$, $4/6=1.5$, $4/6=2.0$) and edema ($4/6=1$, $4/6=1.5$). At 72 hours, $4/6$ had erythema ($4/6=1$) and $4/6$ edema ($4/6=1$). Primary Dermal Irritation Score was 0.8.

Study Classification: Core Guideline Data.

Toxicity Category: IV - CAUTION

Page _____ is not included in this copy.

Pages 5 through 7 are not included.

The material not included contains the following type of information:

- ☐ Identity of product inert ingredients.
 - ☐ Identity of product impurities.
 - ☐ Description of the product manufacturing process.
 - ☐ Description of quality control procedures.
 - ☐ Identity of the source of product ingredients.
 - ☐ Sales or other commercial/financial information.
 - ☒ 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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