Date: February 25, 1987

Subject: EPA File Symbol: 18910-A 006286
Basilit B 85

From: Nelson J. Graham
H16/288 E 2/25/87

To: Lois Rossi
Product Manager (21)

Applicant: Dessowag-Bayer Holzschutz GmbH
Ross Strasse 76, D-4000 Duesseldorf 30
Federal Republic of Germany
c/o George Seidicyn, Calvay Technologies, Inc.
609 Fifth Ave
New York, N.Y. 10017

Active Ingredient:
Boric Acid ($H_3BO_3$) . . . . . 63.2%
Inert Ingredients . . . . . 36.8%

Background: Submitted Acute Oral, Acute Dermal, Eye Irritation and Primary Dermal Irritation Studies to support conditional registration of this product. Studies conducted by Institut für Biologie-Forschungszentrum Seiberdorf. Data under accession numbers: 265146, 265147, 265148, and 265149. Method of support not indicated.

Recommendation:



1 of 9

FHB/SB — E 2/25/87

006286

To: Lois Rossi
Product Manager (21)

Applicant: Desowag-Bayer Holzschutz GmbH
Ross Strasse 76, D-4000 Duesseldorf 30
Federal Republic of Germany
c/o George Bodicky, Solray Technologies, Inc
609 Fifth Ave
New York, N.Y. 10017

Active Ingredient:
Boric Acid ($H_3BO_3$) . . . . . 63.2%
Inert Ingredients . . . . . 36.8%

Background: Submitted Acute Oral, Acute Dermal, Eye Irritation and Primary Dermal Irritation Studies to support conditional registration of this product. Studies conducted by Institut für Biologie Forschungszentrum Seiberdorf. Data under accession numbers: 265146, 265147, 265148, and 265149. Method of support not indicated.

Recommendation:
(1) FHB/SB finds the Acute Oral, and Acute Dermal Studies acceptable to support conditional registration ~~applied~~ of this product.



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(2) The Eye Irritation and Primary Dermal Iritation Studies were not acceptable because & in both studies atleast six animals must be used.

(3) Acute Inhalation and Dermal Sensitization Studies were not submitted. Hese studies must be submitted.

Labelie

(1) Label comments are reserved until acceptable Eye Iritation and Primary Dermal Iritation, Acute Inhalation and Dermal Sensitization Studies are submitted.

Not to PM:

(1) It was brought to my attention that Boric Acid Technical is manufactured for specific use as an insecticide, therefore it is questionable as to whether it can be used to formulate a fungicide. The question of misuse of product should be examined

Review:

(1) Acute Dermal Toxicity Study: Institute für Biologie Forschungszentrum Seibersdorf; Study DBAS; December 19, 1985; EPA Acc. No. 265146.

Procedure: Five male and five female rabbits with intact skin sites were each treated with 2000 mg/kg bw the test material. Treated sites were placed under occlusive wrap for 24 hours exposure. Abbreviations were briefly

must be submitted.

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Labels
1) Label comments are reserved until acceptable Eye Irritation and Primary Dermal Irritation, Acute Inhalation and Dermal Easy Sensitization Studies are submitted.

Not to PM:
1) It was brought to my attention that Boric Acid Technical is manufactured for specific use as an insecticide, therefore it is questionable as to whether it can be used to formulate a fungicide. The question of misuse of product should be examined

Review:
1) Acute Dermal Toxicity Study: Institute für Biologie Forschungszentrum Seibersdorf; Study # DB #5; December 19, 1985; EPA Acc. No. 265146.

Procedure: Five male and five female rabbits with intact skin sites were each treated with 2000 mg/kg of the test material. Treated sites were placed under occlusive wrap for 24 hour exposure. Observations were made for through day 15. Necropsy performed on all animals.

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Results: No mortalities, toxic signs or abnormalities at necropsy. LD50 reported to be greater than 2000 mg/kg.

Study Classification: Core Guideline Data

Toxicity Category: III - CAUTION

(2) Acute Oral Toxicity Study: Institut für Biologie Forschungszentrum Seibersdorf; Study # DBH4; Dec. 19, 1985. EPA Acc. No. 265147.

Procedure: Four groups consisting of five male and five female rats each were dosed with one of the following doses orally: 4220, 5820, 8080 or 11200 mg/kg. Observations made through day 15. Necropsy performed on all animals.

Results: At 4220 mg/kg, 4/5 F died; at 5820 mg/kg, 4/5 M and 2/5 F died; at 8080 mg/kg, 5/5 M and 5/5 F died; at 11200 mg/kg, 5/5 M and 5/5 F died: Toxic signs reported included dyspnoea, diarhoea, retracted flanks, raised fur, fur blood-tinged, lunger, arched back, decreased discharge of faeces, drowsiness, decreased reaction to external stimulation, increased reaction to external stimulation, salivation, lacrimation, ataxia, restlessness, incrusted eyes, mouth and nose. Necropsy report revealed gastro-intestinal tract empty, intestines empty, gastro-intestinal tract full of liquid contents, stomach full of liquid contents, edema, intestinal petechiae, gastroenteritis, folded parietal serosa, nose blood-tinged, exsiccosis, pulmonary edema.



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(2) Acute Oral Toxicity Study: Institut für Biologie Forschungszentrum Leiberstorf; Study # DBH4; Dec. 19, 1985. EPA Acc. No. 265147.

Procedure: Four groups consisting of five males and five female rats each were dosed with one of the following doses orally: 4220, 5820, 8080 or 11200 mg/Kg. Observations made through day 15. Necropsy performed on all animals.

Results: At 4220 mg/kg 4/5 M and 2/5 F died; at 5820 mg/kg 4/5 F died; at 8080 mg/kg 5/5 M and 5/5 F died; at 11200 mg/kg, 5/5 M and 5/5 F died. Toxic signs reported included dyspnoea, diarrhoea, retracted flanks, raised fur, fur blood-tinged, hunger, arched back, decreased discharge of faeces, drowsiness, decreased reaction to external stimulation, increased reaction to external stimulation, salivation, lacrimation, ataxia, restlessness, incrusted eyes, mouth and nose. Necropsy report revealed gastro-intestinal tract empty, intestines empty, gastro-intestinal tract full of liquid contents, stomach full of liquid contents, edema, intestinal petechiae, gastroenteritis, folded parietal serosa, nose blood-tinged, exsiccosis, pulmonary edema, testes retracted to abdominal cavity and perineal region soiled. LD50 for females reported to be 5830 mg/Kg (with 95% confidence limits between 4690 and 7230 mg/Kg), LD50 males reported to be 5280 mg/Kg (4630 - 6020 mg/kg). LD50 for males and females combined reported to be 5520 mg/Kg (4850 - 6270 mg/kg).

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Study Classification: Core Guideline Data

Toxicity Category: IV - CAUTION

(3) Dermal Irritation Study: Institut für Biologie Forschungszentrum Seibersdorf; Study# DBH 6; December, 1985; EPA Acc. No. 265148.

Procedure: Three rabbits with intact skin sites each received a 0.5 ml application of the test material under occlusive wrap for 4 hour exposure period. Observations made for 72 hours post treatment.

Results: No irritation reported throughout 72 hour observation period.

Study Classification: Core Supplementary Data See Item # 2 of Recommendations.

(4) Eye Irritation Study: Institut für Biologie Forschungszentrum Seibersdorf; Study# DBH 7; December 19, 1985; EPA Acc. No. 265149

Procedure: Three rabbits received 0.1 ml of the test material in one eye each. Observation made for 72 hours post treatment.

Results: At 24 hours post treatment, 3/3 had redness (3/3=1). At 72 hours, redness had cleared.

Study Classification: Core Supplementary Data.

Procedure: Three rabbits with intact skin sites each received a 0.5 ml application of the test material under occlusive wrap for 4 hour exposure period. Observations made for 72 hours post treatment.

Results: No irritation reported throughout 72 hour observation period.

Study Classification: Core Supplementary Data See Item # 2 of Recommendations.

(4) Eye Irritation Study: Institut für Biologie Forschungszentrum Seibersdorf; Study # DBH 7; December 19, 1985; EPA Acc. No. 265149

Procedure: Three rabbits received 0.1 ml of the test material in one eye each. Observation made for 72 hours post treatment.

Results: At 24 hours post treatment, 3/3 had redness (3/3=1). At 72 hours, redness had cleared.

Study Classification: Core Supplementary Data. See Item # 2 of Recommendation.

RIN 5117-93 BORIC ACID
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Page 9 is not included in this copy.

Pages _____ through _____ are not included.

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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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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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