

US EPA ARCHIVE DOCUMENT

Date: February 25, 1987

Subject: EPA File Symbol: 18910-A
Basalt B 85

006286

From: Patricia J. Lukam
JHB/ell

E 2/25/87

To: Lois Rossi
Product Manager (21)

Applicant: Dessaug-Bayer, Holzschütz GmbH
Kess-Strasse 76, D-4000 Düsseldorf 30
Federal Republic of Germany
c/o George Pedicini, Salroy 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 Leiberdorf. Data under accession numbers: 265146, 265147, 265148, and 265149. Method of support not indicated.

Recommendation:

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File 128

F 2/25/7

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To: Lois Rossi
Product Manager (21)

Applicant: Dessaug-Bayer Halachutz GmbH
Rosa Strasse 76, D-4000 Düsseldorf 30
Federal Republic of Germany
40 George Bellamy, 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 Seibersdorf. Data under accession numbers: 265146, 265147, 265148, and 265149. Method of support not indicated.

Recommendation:

(1) File 128 finds the Acute Oral, and Acute Dermal studies acceptable to support conditional registration of this product.

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

(3) Acute Inhalation and Dermal Irritation Studies were not submitted. These studies must be submitted.

Labels:

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

Note to PM:

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 for Biologie Forschungszentrum Jecherology; Study # DBHS; December 19, 1985; EPA Acc. No. 265146.

Procedure: Five male and five female rabbits with intact skin sites were each treated with 5000 mg/kg ip of the test material. Treated sites were placed under occlusive wrap for 24 hours of exposure. Observations were made

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Label:

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

Note 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
Jochimszentrum Leherdorf; 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 3000 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 mortality, 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 Forschungsinstitut Seibersdorf; 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 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 dyspnea, diarrhea, retracted flanks, raised fur, fur blood-tinged, hunger, arched back, decreased discharge of feces, drowsiness, decreased reaction to external stimulation, increased reaction to external stimulation, calcification, lacrimation, ataxia, restlessness, irritated eyes, ~~and~~ 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, gastritis, folded peritoneal serosa, nose blood-tinged; excruciating pulmonary edema.

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Acute Oral Toxicity Tests: Institut Air Biologie
Zürcher Universität, Liebefeld; 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 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.

Typic 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, uncast eyes, ~~and~~ 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 peritoneal serosa, nose blood-tinged, epistaxis, pulmonary edema, testes retracted to abdominal cavity and perineal region sealed. 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 Supplemental 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 posttreatment.

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 posttreatment.

Results: At 24 hours posttreatment, 7/3 had redness (7/3=1). At 72 hours, redness had cleared.

Study Classification: Core Supplementary Data

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Procedure: Three rabbits with intact skin sites each received a 0.5 ml application of the test material under occlusion for a 4 hour exposure period. Observations made for 72 hours posttreatment. 905286

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 Liberales, 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 posttreatment.

Results: At 24 hours posttreatment, 7/3 had redness (7/3=1). At 72 hours, redness had cleared.

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

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RIN 5117-93

BORIC ACID

Tox Review 006286

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Pages _____ through _____ 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.
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