

US EPA ARCHIVE DOCUMENT

DATE: January 13, 1981

000455

589

SUBJECT: EPA Registration. Symbol: 8568-RR  
Dip' n Grow: Caswell # \_\_\_\_\_

FROM: Deloris F. Graham *D.F.G. 1/21/81*  
FHB/TSS *E 1/21/81*

000455

TO: Robert Taylor  
Product Manager (25)

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Applicant: C-R Chemical Research Company  
11040 S.E. Mill Court  
Portland, Oregon 97216

Active Ingredient:  
Indole-3-butyric acid.....1.0%  
1-Naphthaleneacetic acid.....0.5%  
Inert Ingredients.....98.5%

Background: Submitted Acute Dermal Toxicity data as requested in the original review.

Recommendations:

- (1) FHB/TSS finds this data acceptable to support the conditional registration of this product.
- (2) In an Acute Dermal Toxicity study a 2g/kg dose must be used and in a Primary Dermal Study 0.5g/kg must be used. Since no toxic or pharmacologic signs were evident at a 2g/kg dose, ~~therefore it is~~ <sup>TSS</sup> of the scientific opinion that data gained in a study using 0.5g/kg would show no additional hazard.
- (3) Please see enclosed copy of "Proposed Guidelines" section 163.81-1 thru 5 for correct testing and reporting procedures.

(4) *The appropriate signal word is CAUTION.*

Label:

- (1) No additional labeling comments.

Review:

- (1) Acute Dermal Toxicity: Willamette Laboratories

Procedure: 5M and 5F rabbits received a 2g/kg dose at abraded skin site. Treated skin sites were placed under occlusive wrap for 24-hour exposure. Observations made daily for 14 days.

Results: 3/10 animals exhibited cutaneous ulcers and subcutaneous abscess. The skin of the remaining seven animals was intact with no evidence of inflammation. The abdomen showed evidence of recent shaving but no abrasions were noted at the time of autopsy. No visible abnormalities noted at autopsy, other than cutaneous ulcers present in 3 animals. One animal sacrificed on the 11th day.

Study Classification: Core Minimum Data

Toxicity Category: III - CAUTION

Indole-3-butyric acid toxicology review

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Page 3 is not included in this copy.

Pages \_\_\_\_\_ through \_\_\_\_\_ are not included in this copy.

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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 product 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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