DATE: January 13, 1981

SUBJECT: EPA Registration Symbol: 8568-RR
Dip' n Grow: Caswell #_____

FROM: Deloris F. Graham DFG 1/21/81
FHB/TSS
E 1/21/81

TO: Robert Taylor
Product Manager (25)

000455

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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-Naphthaleneactic 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~~ TSS 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 Minimium Data

Toxicity Category: III - CAUTION

Indole-3-butyric acid toxicology review

Page 3 is not included in this copy.

Pages _____ through _____ are not included in this copy.

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

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

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.