DATE: January 13, 1981

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

FROM: Deloris F. Graham
FHB/TSS

TO: Robert Taylor
Product Manager (25)

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 TSS pharmacologic signs were evident at a 2g/kg dose, therefore it is 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

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.