5-12-93

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FIFRA

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OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

Subject: EPA File Symbol: 1812-GUT

From: Mark J. Perry, Biologist
Precautionary Review Section
Registration Support Branch
Registration Division (H7505C)

MJP 5-12-93

To: Cynthia Giles-Parker, PM 22
Fungicide-Herbicide Branch
Registration Division (H7505C)

Thru: Thomas C. Ellwanger, Section Head
Precautionary Review Section
Registration Support Branch
Registration Division (H7505C)

Mary Waller for T.E. 5/12/93

Applicant: Griffin Corp.
P.O. Box 1847
Valdosta, GA 31603-1847

FORMULATION FROM LABEL:

	% by wt.
Active Ingredient(s): Copper Hydroxide	88.0
Inert Ingredient(s):	12.0
Total:	100%

BACKGROUND

Griffin Corporation submitted acute oral, acute dermal, acute inhalation, eye irritation, dermal irritation and dermal sensitization studies for review. The product is Spin Out Powder, a root control additive for fiber plant pots, and the active ingredient is copper hydroxide (88.0%). All studies except the inhalation and eye irritation were performed by Arthur D. Little Inc., and the MRID numbers are 422352-01 through 422352-03 and 425091-01. The inhalation and eye studies were performed by Springborn Laboratories; the MRID numbers are 424812-01 and 402374-02.

Initial study reviews were performed by Clement International.

RECOMMENDATION

1. Acute Oral: II/Minimum

•Most of the female test animals were significantly below the acceptable weight range of 200-300 grams.

2. Acute Dermal: III/Minimum

•The test material was applied to a gauze patch prior to application to each test animal. Proper application involves the test material being applied uniformly over the exposure site, i.e., directly to the animal.

3. Acute Inhalation: II/Minimum

•The chamber humidity varied well beyond the range specified in the Pesticide Assessment Guidelines.

4. Eye Irritation: I/Guideline

5. Dermal Irritation: Supplementary

•The Pesticide Assessment Guidelines require solid materials to be "slightly moistened" prior to application. This means that the test material should be moistened with a minimal amount of vehicle, not "diluted" to form a concentration of less than 50% test material as in the subject study. PRS believes that this dilution may have significantly reduced the irritancy potential of the test material.

6. Dermal Sensitization: Supplementary

•The test material concentration selected for induction was not sufficient to adequately stimulate the animal immune systems. For induction, a dose should be employed which produces mild to

moderate irritation in order to enhance test sensitivity and ensure that the animals are adequately exposed to the test material. The concentration employed in the subject study produced only scattered mild redness in three test animals.

•The dose volume applied during the induction and challenge exposures was not reported.

•The subject study states that the "maximum non-irritant concentration was 50%." According to the results of the range-finding study, however, the 50% concentration does not meet the Buehler definition of the highest non-irritating concentration. Buehler defines the highest non-irritating concentration as that concentration which results in reactions no more severe than very faint erythema (Draize grade 1) in two of four animals at 24 hours. The 50% concentration in this study resulted in no erythema at each 24 hour reading during the range-finding phase. Therefore, this concentration (50%) does not meet the criteria for the highest non-irritating concentration and should not have been considered appropriate for challenge.

7. Since the above studies were performed with copper hydroxide technical rather than the end use product formulation for Spin Out Powder, they do not support product registration. The end use formulation contains [redacted] is highly corrosive and its absence in the test material may have affected the study results. Therefore, PRS requires acute oral, acute dermal, acute inhalation, dermal irritation and dermal sensitization studies performed with the end use formulation of Spin Out Powder to support registration of this product. A new eye irritation study is not required since a category I result has been demonstrated.

INERT INGREDIENT INFORMATION IS NOT INCLUDED

LABELING

1. Precautionary labeling for Spin Out Powder will be determined following the submission of the requested studies.

2. Due to eye irritation, this end use product meets the criteria for restricted use classification. The PM should decide if the label contains sufficient alternative labeling language to offset the hazard and the need for this classification.

ACUTE TOXICITY PROFILE (Spin Out Powder)

Acute Oral	Requested
Acute Dermal	Requested
Acute Inhalation	Requested
Eye Irritation	Category I/G
Dermal Irritation	Requested
Dermal Sensitization	Requested